UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

KING COUNTY and CITY OF TACOMA, individually and on behalf of others similarly situated,

Plaintiffs,

v.

TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA NEUROSCIENCE, INC.,

Defendants.

No. 2:21-cv-00477

**COMPLAINT— CLASS ACTION**

**JURY DEMAND**



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Plaintiffs, individually and on behalf of all others similarly situated, bring this Class Action Complaint against Defendants Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Teva Neuroscience, Inc. (collectively, "Teva" or "Defendants") and allege the following based upon personal knowledge, information and belief, and investigation of counsel:

## I. INTRODUCTION

1. This case concerns a pharmaceutical company's decade-long campaign to manipulate doctors, pharmacies, benefit managers, and patients in order to unfairly and deceptively induce health plans in the United States to pay billions for its excessively priced multiple sclerosis drug.

2. Multiple sclerosis ("MS") is a debilitating disease that causes the body's immune system to attack the central nervous system. Patients with MS experience a range of symptoms, including fatigue, weakness, vision problems, and cognitive deficits. The most common form of MS, relapsing-remitting multiple sclerosis ("RRMS"), is characterized by clearly defined attacks of new or increasing symptoms followed by periods of remission, during which symptoms partially or completely subside.

3. Glatiramer acetate is an injectable drug that has been approved by the U.S. Food and Drug Administration ("FDA") to treat RRMS. Glatiramer acetate simulates the protective protein that surrounds nerve fibers and thus blocks or otherwise interrupts the immune system attacks associated with RRMS. While glatiramer acetate helps alleviate symptoms of MS, there is no known cure for MS. As a result, many patients remain on glatiramer acetate for many years.

4. Although Teva did not develop glatiramer acetate, it has licensed the rights to the drug since 1987 and has held all patents on the drug. In 1997, following approval from the FDA, Teva began selling glatiramer acetate under the brand name Copaxone.

5. When Teva first began selling Copaxone in 1997, it set the price for a *monthly course of treatment at $769.15*. That price remained until 2000, after which Teva began annual



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price increases that resulted in a price of approximately $1000 per month by 2003. However, that was only the beginning of Teva's increasingly aggressive pricing strategy that saw Teva increase the price of Copaxone *twenty-seven times* by the time it reached a monthly cost of *$5,832 by 2017*.

6. A September 2020 report from the United States House Committee on Oversight and Reform concluded that Teva's costs did not come anywhere close to justifying these price increases.[1] Rather, Teva reaped excessive profits from Copaxone. Between 2002 and 2019, Teva's net revenue from Copaxone sales in the United States alone exceeded $34 billion.

7. Incredibly, Teva was able to increase prices—and obtain these massive profits—without losing sales to more affordable MS treatments, including generic versions of glatiramer acetate. Teva accomplished this feat by cheating the U.S health insurance system.

8. The ultimate targets of its scheme were the numerous employers and insurers who pay claims on behalf of the hundreds of millions of Americans who are covered by health benefit plans. Put simply, Teva preyed upon the fundamental disconnect between the entities that pay for prescription medications (employers and insurers who pay claims incurred by health plan members) and the individuals and entities that determine which products are ultimately purchased (doctors, pharmacists, benefit managers, and health plan members). Teva used myriad unfair and deceptive practices to manipulate the individuals and entities that selected products, knowing these individuals were mostly (if not entirely) ambivalent to the cost of Copaxone. It manipulated the prescribing decisions of doctors, the product selection decisions of pharmacists, the drug prioritization decisions of pharmacy benefit managers, and the purchasing decisions of health plan members. By causing these entities to select Copaxone instead of alternative, lower cost MS treatments, Teva induced employers and insurers to pay for—and continue paying for—Copaxone despite its ever-increasing price.

[1] Staff of H.R. Comm. on Oversight and Reform, 116th Cong., Drug Pricing Investigation Teva-Copaxone (Sept., 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf ("House Report").



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9. The scheme consisted of multiple components. ***First***, Teva manipulated the purchasing decisions of health plan members by circumventing the cost-sharing obligations that health plans impose on members to make them sensitive to price. Most health plans require members to pay co-insurance or copayments, which represent a portion of the purchase price of prescription drugs and other medical care. These payments are designed to make members at least partially internalize the cost of prescriptions so they will prefer more affordable treatment options and not cause plan payors to incur excessive costs. Given these cost-sharing arrangements, Teva knew plan members would prefer more affordable treatment options, including lower cost generic versions of glatiramer acetate. Rather than making the price of Copaxone more affordable, Teva instead interfered with plan cost-sharing arrangements.

10. Specifically, Teva provided health plan members with "coupons" that relieved them of some or all of their cost-sharing obligations if they purchased Copaxone. This meant that for health plan members, Copaxone would be less expensive than other treatments, including generics. Unfortunately, for health plan payors—the entities that pay the bulk of the cost for all prescriptions—Copaxone remained excessively priced. Teva thus induced health plan payors to continue paying for Copaxone by manipulating health plan members and circumventing health plan design.

11. As detailed below, for Teva to be able to maintain high prices without losing sales, it would have to extend this form of "copay assistance" to the vast majority of health plan members in the United States, including Medicare recipients and members of private health plans. To pull off such an elaborate scheme, Teva conspired with specialty pharmacies, non-profit foundations, and other entities and engaged in a variety of illegal, unfair, and deceptive acts.

12. ***Second***, Teva manipulated pharmacists by circumventing drug substitution laws. Drug substitution laws allow or require pharmacists to substitute generic versions for a prescribed brand name drug. These laws play an important role in lowering health plan costs, as



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they typically cause health plans to pay for lower costs generics instead of higher cost brand versions of the same drug. But these laws allow substitution only if generics are "therapeutically equivalent" to the brand drug, including if they are of the same form, dosage, and strength. When Copaxone was nearing the end of its patent exclusivity, Teva launched a new 40 mg/ml, three-times-a-week formulation to avoid drug substitution laws. Teva, in collusion with pharmacy benefit managers, then resorted to unfair and deceptive tactics to coerce and persuade patients and doctors to switch to the new dosage, which enjoyed extended patent exclusivity. As a result, even when generic forms of 20mg glatiramer acetate were available for sale in the United States, the majority of health plan members were being prescribed 40mg Copaxone. And because 40mg Copaxone is a different dosage than 20mg glatiramer acetate, pharmacists could not substitute the more affordable generic.

13. ***Third***, when 40mg generic glatiramer acetate entered the market after Teva's patent on the new dosage was invalidated, Teva implemented a multi-pronged offensive to ensure that health plan members continued to receive—and health plan payors continued to pay for—its excessively priced Copaxone products. It extensively lobbied doctors to write prescriptions with a "dispense as written" notation, which precluded pharmacists from substituting with available generics. It conspired with pharmacy benefit managers to make Copaxone the favored form of glatiramer acetate under drug "formularies," the prioritized lists of drugs covered by health benefit plans. It conspired with specialty pharmacies, which agreed to fill prescriptions with Copaxone even if the prescriptions were written for a lower cost generic. And it engaged in an elaborate outreach campaign to health plan members—who, because of Teva's copay assistance program, were not sensitive to price—to persuade them to request their doctors keep writing prescriptions for brand name Copaxone with the "dispense as written" notation.

14. The end result was that health plan payors unnecessarily expended billions of dollars on Copaxone. But for the illegal, unfair, and deceptive conduct of Teva and its co-



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conspirators, Teva would have been forced to lower the price of Copaxone and health plan payors would have spent far less on MS treatments, as they would have paid for either more affordably priced Copaxone or other lower cost alternatives.

15. Plaintiffs King County and the City of Tacoma sponsor self-funded health benefit plans for their employees, which means they pay for their employees' prescription medications. When prescription drugs are overpriced, King County and Tacoma pay the inflated prices. King County and Tacoma paid more for Copaxone than they would have spent on MS treatments but for Teva's deceptive and manipulative conduct.

16. Plaintiffs bring this action to hold Teva accountable for its unfair, manipulative, and deceptive actions to obtain excessive profits on a critical treatment for a debilitating disease. This conduct violates the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq*. and the Washington Consumer Protection Act, RCW 19.86 *et seq*., and has unjustly enriched Teva. Plaintiffs seek to recover damages and overpayments from at least 2006 through the present, and to obtain appropriate injunctive relief to cease this harmful conduct. Plaintiffs also seek treble damages, attorneys' fees, costs, and punitive damages.

## II. JURISDICTION AND VENUE

17. This Court has subject-matter jurisdiction over Plaintiffs' federal claims pursuant to 28 U.S.C. § 1331 (federal question) and 18 U.S.C. § 1964 (RICO) and has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. §1367.

18. This Court also has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 (exclusive of interest and costs), the number of the members of the Class exceeds 100, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants.

19. The Court has personal jurisdiction over Defendants because they conduct business in Washington, have purposefully directed their actions toward Washington, and have



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sufficient minimum contacts with Washington. Defendants intentionally avail themselves of the markets in this State through the promotion, marketing, and sale of the products at issue in this lawsuit. Moreover, Plaintiffs' claims arise out of, or relate to, Defendants' contacts with the State of Washington.

20. Venue is proper in the Western District of Washington pursuant to 28 U.S.C. § 1391 (b)(2) and (3) because a substantial part of the events or omissions giving rise to the claims at issue in this Complaint arose in this District and Defendants are subject to the Court's personal jurisdiction with respect to this action.

## III. PARTIES

### A. Plaintiffs

21. Plaintiff King County is a Washington County organized and existing under the laws of the State of Washington, RCW 36.01 *et seq.* King County provides health insurance for its employees and their beneficiaries through self-insured health plans. King County purchases, pays for, and/or provides reimbursement for some or all of the purchase price of prescription drugs dispensed to members of its plans. King County purchased, paid for, and/or provided reimbursement for some or all of the purchase price of Copaxone prescriptions prescribed to members of its plans. King County continues to purchase, pay for, and/or provide reimbursement for some or all of the purchase price of Copaxone prescriptions dispensed to members of its plans.

22. Plaintiff City of Tacoma ("Tacoma") is located in Pierce County, Washington. Tacoma is incorporated as a first-class city pursuant to RCW 35.22 *et seq.*, as it has a population of ten thousand or more inhabitants and has adopted a charter in accordance with Article XI, section 10 of the State of Washington's constitution. Tacoma provides health insurance for its employees and their beneficiaries through self-insured health plans. Tacoma purchases, pays for, and/or provides reimbursement for some or all of the purchase price of prescription drugs dispensed to members of its plans. Tacoma purchased, paid for, and/or provided reimbursement



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for some or all of the purchase price of Copaxone prescriptions prescribed to members of its plans. Tacoma continues to purchase, pay for, and/or provide reimbursement for some or all of the purchase price of Copaxone prescriptions dispensed to members of its plans.

**B. Defendants**

23. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd.'s shares are publicly traded in the United States.

24. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), is a Delaware corporation with its principal place of business in Parsippany, New Jersey. Teva USA is a wholly owned subsidiary of Teva Ltd.

25. Defendant Teva Neuroscience, Inc. ("Teva Neuroscience"), is a Delaware corporation with its principal place of business in Overland Park, Kansas. It is a wholly owned subsidiary of Teva USA.

26. For purposes of clarity, Plaintiffs herein collectively refer to Teva Ltd., Teva USA, and Teva Neuroscience as "Teva." Teva manufacturers, markets, and sells Copaxone throughout the United States.

## IV. FACTUAL BACKGROUND

**A. Multiple Sclerosis**

27. Multiple Sclerosis ("MS") is an immune-mediated disease that causes the body's immune system to attack the central nervous system (the brain, spinal cord, and optic nerves). It is estimated that more than 900,000 people in the United States live with MS.

28. The most common form of MS is relapsing-remitting multiple sclerosis ("RRMS"), with approximately 85 percent of all MS patients being initially diagnosed with RRMS. Patients suffering from RRMS experience clearly defined attacks of new or increasing neurologic symptoms, which are known as relapses or exacerbations. These attacks eventually



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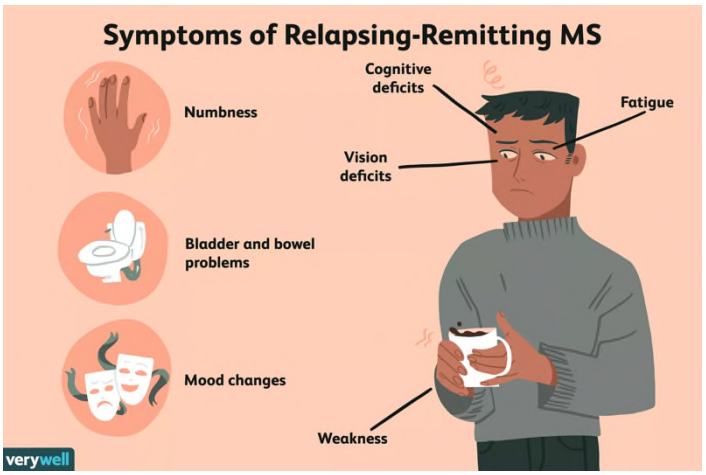
subside and are followed by remissions, during which some or all symptoms disappear (though other symptoms may continue or become permanent).

29. Relapses are caused by inflammatory attacks on myelin, which is a protein that covers and protects the nerve fibers in the central nervous system. These inflammatory attacks occur when certain of the body's immune cells, specifically T-cells, begin to attack myelin, as well as the nerve fibers themselves, in small, localized areas. When myelin or nerve fibers are damaged, messages within the central nervous system become disrupted, causing a variety of symptoms. The particular symptoms of a relapse depend on which areas of the central nervous system are attacked by these T-cells.

30. During relapses, symptoms may include fatigue, numbness, vision deficits, cognitive deficits (problems with learning, memory, or information processing), weakness, spasticity or stiffness, and bowel and bladder problems.




31. The cause of MS is unknown, but it is believed that environmental and genetic factors increase the risk of developing the disease.

32. MS is more prevalent in areas farther from the equator. Some researchers believe this is related to vitamin D: people living closer to the equator are exposed to more sunlight, exposure to sunlight is known to cause the skin to produce vitamin D, and evidence indicates that low vitamin D levels increase the risk of developing MS.



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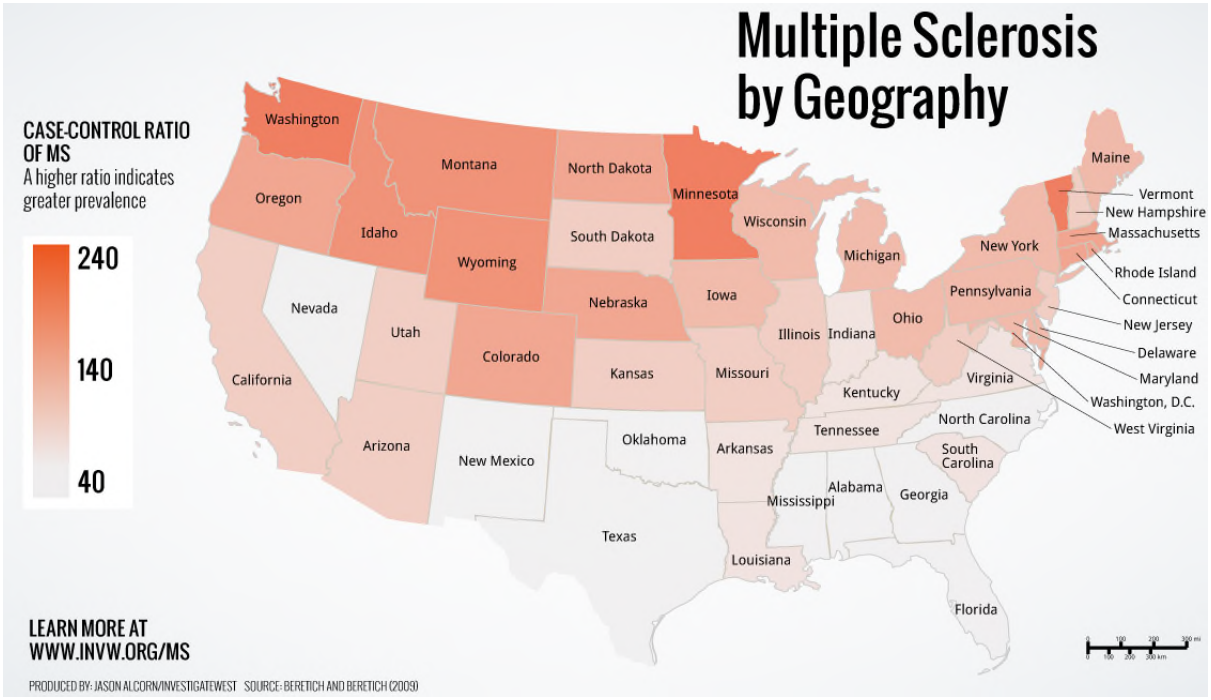
33. MS is particularly prevalent in northern states, including Washington.




34. While MS afflicts approximately one in 1,000 Americans on average, the rate of prevalence is considerably higher in Puget Sound. For example, as of 2012, there were 9,000 known cases of MS in King County, meaning that MS afflicts approximately 1 in every 223 residents.[2]

**B. Copaxone**

35. Copaxone is an injectable drug approved by the FDA to treat relapsing forms of MS, including RRMS. The active ingredient in Copaxone is glatiramer acetate, a chemically synthesized protein that simulates myelin. While glatiramer acetate does not cure MS, it is a disease-modifying therapy ("DMT") that helps reduce relapses by blocking T-cells or otherwise interrupting the immune system attack.

36. Although there are other DMT's approved by the FDA to treat relapsing forms of MS, these various DMTs use different mechanisms of action and routes of administration and are

[2] Carol Smith, *Search For Cause Of High Rates Of MS In Northwest Could Lead To New Treatments*, KUOW (Nov. 27, 2012 6:20 AM), https://www.kuow.org/stories/search-cause-high-rates-ms-northwest-could-lead-new-treatments



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thus not therapeutically interchangeable. Since 2008, glatiramer acetate has been the DMT that is most commonly prescribed to treat relapsing forms of MS.

37. Teva Ltd. licensed the rights to Copaxone from the Weizmann Institute of Science in 1987 and is or was the owner of glatiramer acetate patents.

38. Teva USA is the exclusive U.S. licensee of glatiramer acetate patents.

39. The Food and Drug Administration approved Copaxone for treatment of RRMS in 1996.

40. Teva began selling Copaxone in March 1997.

41. Copaxone is Teva's leading brand name pharmaceutical product. "In 2015, Copaxone® revenues … amounted to $3.2 billion in the U.S. (approximately 29% of Teva's total 2015 U.S. revenues)."[3] Copaxone accounted for nearly one-fifth of Teva's North America net revenue between 2017 and 2019. House Report Executive Summary ("House Exec Summ") at i.

**C. Teva Drastically Increased the Price of Copaxone**

42. Teva has raised the price of Copaxone *27 times* since first releasing the drug in 1997. Teva increased the price of a yearly course of Copaxone from $10,000 in 1997 to nearly $70,000 today. House Exec Summ at i.

[3] Teva Ltd., 2015 Annual Report (Form 20-F), Notes to Consolidated Financial Statements, F-64, https://www.sec.gov/Archives/edgar/data/818686/000119312516459785/d120587d20f.htm.



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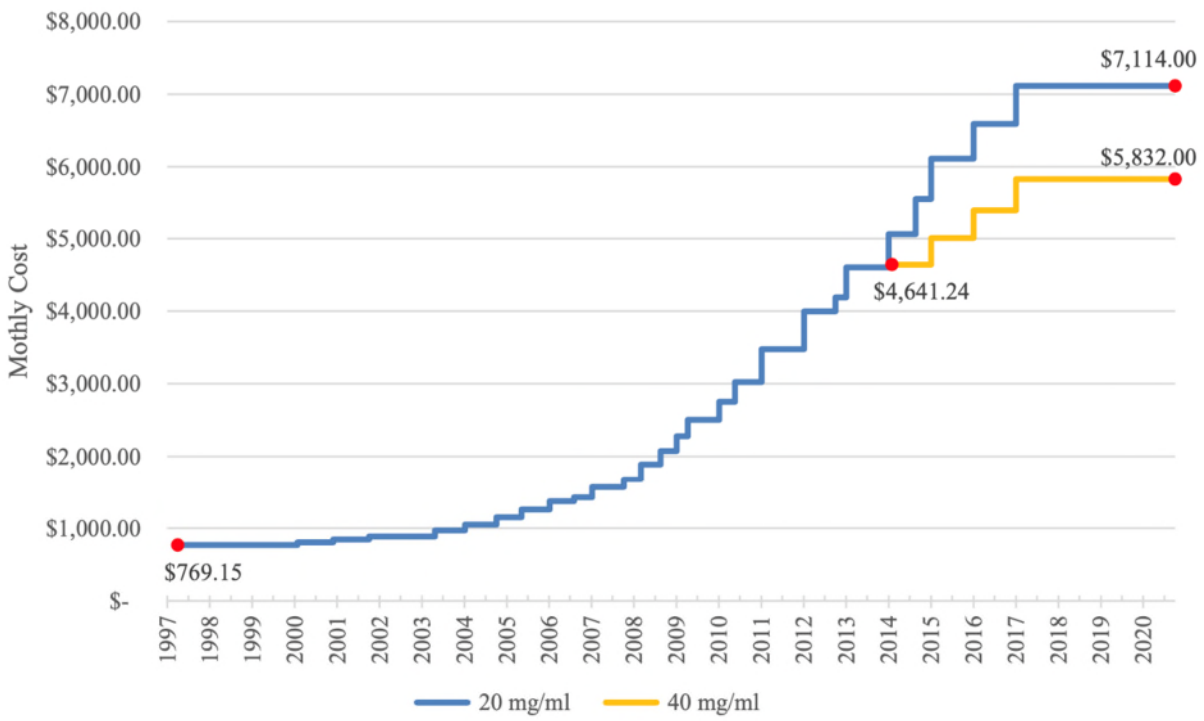
43. The following chart shows the increase in the monthly cost of Copaxone over time:




44. The prices Teva charged for Copaxone in the United States far exceeded the prices it charged in other countries. In 2015, the net price of Copaxone 40mg/ml was $126 per day in the United States. In stark contrast, this same daily dosage was only $33 in Germany, $26 in Spain, $25 in the United Kingdom, and $18 in Russia. House Exec Summ at i.

45. As the House Committee on Oversight and Reform found, "[e]ven Teva's own employees could not afford Copaxone at its price." In one July 2018 exchange uncovered by House investigators, a Teva employee explained that she could no longer afford Copaxone because she would have to pay $1,673.33 out of pocket, far greater than the $12 it would have cost her to buy Mylan's generic version of the same drug. *Id.* at ii.

46. As consumers and health plans paid increasingly excessive amounts for this critical MS medication, Teva's executives obtained massive payouts. Top executives were paid



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more than $190 million between 2012 and 2017, the years during which Teva's Copaxone revenues were highest. *Id.* at i.

47. The House Oversight Committee reviewed Teva's internal data, which revealed that the price increases could not be explained by increased rebates, discounts, of other fees paid to pharmacy benefit managers (PBMs) or other entities in the pharmacy distribution chain. Teva's net revenue (after such rebates and discounts) increased from 2009 to 2017. *Id.* at v.

48. The House Oversight Committee also found that "Teva invested only a small portion of its Copaxone revenue in further research and development to help Copaxone patients." *Id*. Teva invested only $689 million in Copaxone related research and development since 1987, which is only 2% of the $34.2 billion in net U.S. revenue it obtained from Copaxone between 2002 and 2019. *Id.*

**D. Pharmaceutical Industry Overview**

49. Teva was able to dramatically increase the price of Copaxone without losing sales because it manipulated several unique aspects of the U.S. pharmaceutical market. The following section provides an initial overview of a few key concepts necessary to understanding Teva's misconduct.

50. ***Pharmaceutical Distribution chain*:** Pharmaceutical companies like Teva—also referred to herein as "drug companies" or "manufacturers"—develop, manufacture, market, and sell prescription drugs. Pharmaceutical companies sell their prescriptions drugs to wholesalers, who purchase drugs in bulk and distribute them to pharmacies and hospitals. Pharmacies typically purchase prescription drugs from wholesalers to dispense to consumers.

51. There are two main types of pharmacies: retail and specialty. Retail pharmacies dispense most common medications and include chain pharmacies (*e.g.*, Walgreens and CVS), pharmacies in grocery stores and other retailers (e.g., Walmart, and Costco), hospitals, and independently owned pharmacies. Specialty pharmacies dispense medications used to treat relatively rare or complex health conditions, as well as medications that require special handling,



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are administered through injection or IV, or require special instruction or follow-up care from a pharmacist or other health care professional. Copaxone, like most MS therapies, is typically considered to be a specialty drug and is typically dispensed through specialty pharmacies.

52. ***Health Insurance:*** People with health insurance in the United States have either public or private health insurance. Public insurance refers to insurance provided by federal and state governments, including Medicare, Medicaid, the Children's Health Insurance Program, and health insurance provided through the Department of Veterans Affairs. Private health insurance refers to insurance that employers offer to their employees as well as insurance purchased directly by patients, including through health exchanges under the Affordable Care Act. As used herein, "private health insurance" includes health plans offered by cities, towns, municipalities or counties that provide health insurance for their employees. The majority of insured individuals in the United States (68.0 percent) have private health insurance, with the overwhelming majority of these individuals receiving health insurance through an employer.[4]

53. There are typically two forms of private health plans: insured plans and employer self-funded (or self-insured) plans. In the case of insured plans, plan members and/or employers pay premiums to an insurance company, which pools premiums to pay claims on behalf of plan members, and bears the risk or covering claims if the pooled premiums are insufficient to pay claims. In the case of self-funded plans, an employer provides health insurance for its employees by setting aside funds that are used to directly pay medical and prescription drug claims. While such an employer will typically contract with an insurance company that will provide administrative services, the employer pays claims and bears the risk for paying claims even if the cost of claims exceeds the funds it has set aside. As used herein, "payor" refers to the insurer (in the case of insured plans) or employer (in the case of employer self-funded plans) that is responsible for paying claims on behalf of plan members.

[4] Katherine Keisler-Starkey and Lisa N. Bunch, *Health Insurance Coverage in the United States: 2019*, U.S. Census Bureau (Sept. 2020), https://www.census.gov/content/dam/Census/library/publications/2020/demo/p60-271.pdf.



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54. ***Pharmacy Benefit Managers:*** A health benefit plan (or the insurance company that insures and/or administers the plan) typically enters into a contract with a pharmacy benefit manager ("PBM") that manages and administers prescription drug benefits on behalf of the plan. According to the PBM trade association, the Pharmaceutical Care Management Association ("PCMA"), PBMs administer prescription drug benefits for more than 266 million Americans. The three largest PBMs—CVS Caremark, Express Scripts, OptumRx—administer prescription drug benefits for more than 200 million Americans.

55. A PBM will create a network of pharmacies that will fill prescriptions at an agreed upon percentage discount from drug list prices. When a health plan member brings a prescription to a pharmacy, the pharmacy contacts the PBM, which will then process and adjudicate the prescription claim. This process entails determining whether the drug is covered under the member's plan and communicating to the pharmacy the portion of drug cost that will be covered by the plan and the portion that the pharmacy must collect from the plan member as coinsurance or copayment. The PBM pays the pharmacy for the plan's portion of the drug cost, later collecting payment from the payor for all drug claims paid on its behalf.

56. PBMs also design drug formularies, which are tiered lists of drugs that indicate which drugs will be covered by plans and which drugs will be preferred over others for various medical conditions. Pharmaceutical companies often pay PBMs "rebates" or other monetary payments in exchange for PBMs agreements to place their drugs at more preferred positions on these formularies.

57. Many PBMs own or are otherwise affiliated with specialty pharmacies and plan members are often required to use the specialty pharmacy owned by or affiliated with their PBM. For example, members of plans serviced by Express Scripts are typically directed or required to fill their specialty prescriptions through Accredo or CuraScript, Express Scripts' wholly owned subsidiaries. Likewise, members of plans serviced by CVS are typically directed or required to fill their specialty prescriptions through CVS Specialty pharmacy and members of plans serviced



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by OptumRx are typically directed or required to fill their specialty prescriptions through Optum Specialty Pharmacy (which was formerly known as BriovaRx).

58. ***Drug Pricing*:** A drug's list price is set by the manufacturer and is the price at which the manufacturer sells the drug to wholesalers. This list price is reported publicly as the "Wholesale Acquisition Cost" ("WAC"), which is a single benchmark price that applies market wide in the United States. A related benchmark, "Average Wholesale Price" ("AWP"), reflects the average price paid by retailers to purchase a drug from wholesalers. AWP is typically set at 120% of the WAC. The prices paid by health plan payors and participants are set as a percentage of one of these benchmarks and are thus determined by the list price set by manufacturers.

59. ***Brand vs. Generics***: The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), governs the manufacturing, sale, and marketing of pharmaceuticals in the United States. Under the FDCA, a company that wants to sell a new drug must submit a New Drug Application ("NDA") to the FDA and provide scientific data demonstrating that the drug is safe and effective for a specific indication. *See id.* § 355(b)(1). The process to obtain FDA approval for an NDA is lengthy and very expensive.

60. To incentivize drug development, branded drug manufacturers protect their products from competition through an FDA-designated exclusivity period. New drugs are typically granted a five-year exclusivity period upon approval. Additionally, drug manufacturers are allowed to protect their new products through patents granted by the US Patent and Trademark Office. These patents are listed in the FDA's "Orange Book," *Id.* at § 355(b)(1), (c)(2), which lists all FDA-approved prescription drugs, their approved generic equivalents, and any patents that purportedly protect each drug. Exclusivity periods and patent protection periods often overlap, but can differ in lengths.

61. Drug patents typically last twenty years and can be obtained at any point in the drug discovery and development cycle for any number of chemical and product features. The FDA-exclusivity period is granted when a drug is first approved. Both the patent system and the



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exclusivity period create incentives for drug innovation by allowing drug innovators to recoup their initial research and development costs and make a substantial profit on top.

62. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, known commonly as the Hatch-Waxman Act ("Hatch-Waxman"), to facilitate competition from low-price generic drugs while maintaining the incentive for companies to research and develop new products. Hatch-Waxman permits generics to come to market as soon as brand drugs lose patent protection, and it encourages generic manufacturers to challenge the scope and validity of existing brand patents.

63. Once the FDA has approved a brand drug, Hatch-Waxman allows a generic manufacturer to obtain similar approval by filing an Abbreviated New Drug Application ("ANDA") specifying that the generic has the same active ingredient and is "biologically equivalent" ("bioequivalent") to the reference brand drug. The ANDA application process allows generic manufacturers to rely on a reference drug's original clinical studies, thereby reducing the cost and time necessary to bring a generic drug to market.

64. Price is the only material difference between generic drugs and their corresponding brand versions. Because generic versions of a corresponding brand drug product are commodities that are not differentiated through advertising or other means, the primary basis for generic competition is price.

65. Generic drugs, on average, cost 80-85% less than their brand-name counterparts.

66. It is widely known among pharmaceutical companies—and the Wall Street analysts and traders who determine their stock prices—that "generic drugs quickly take sales from brand drugs. Once a generic enters the market, a brand loses 44% to 90% of its market share within the first twelve months."[5]

[5] Michael A. Carrier, et al., "*Citizen Petitions: Long, Late-Filed, and At-Last Denied*," 66 AM. U. L. REV. 305, 312 (Dec. 2016), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi? article=1956&context=aulr&httpsredir=1&referer=.



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**E. Teva's Illegal, Unfair, and Deceptive Acts**

67. On September 30, 2020, the House Committee on Oversight and Reform ("House Committee") released findings from its investigation of Teva's pricing of Copaxone, which were based on the Committee's review of more than 300,000 pages of internal documents, communications, and data. House Exec Summ at i. The House Committee's report details several aspects of Teva's misconduct, including how Teva inflated the price of Copaxone and manipulated decisionmakers at all levels of the U.S. healthcare system to cause health plan payors to continue to pay for Copaxone despite its inflated price and despite the availability of lower cost alternatives, including generics.

68. The House Committee found that Teva Ltd. specifically "targeted the U.S. market for price increases while maintaining or cutting prices for the rest of the world." *Id.* Indeed, the House Committee uncovered internal documents in which Teva boasted of its ability to "increase prices successfully," which was "influenced heavily by US [Teva's U.S. Business] being allowed to hike prices." *Id.*

69. Teva has conspired with specialty pharmacies, non-profit foundations, PBMs, physicians, and other persons and entities throughout the U.S. healthcare system to effectuate an ongoing campaign to induce health plan payors to pay for excessively priced Copaxone instead of more affordable, alternative MS treatments. Teva and its co-conspirators were able to induce these payments by manipulating the purchasing decisions of health plan members and the prescribing decisions of physicians, and by restricting the ability for pharmacies to fill prescriptions with lower cost generics. Because Teva was able to induce health plan payors to continue purchasing Copaxone despite its high price, Teva was able to continue to increase and maintain the high price of Copaxone even after generic alternatives entered the market.

70. As detailed below, these efforts were multi-faceted. First, Teva and its co-conspirators executed an illegal and deceptive copay assistance campaign to side-step key cost controls imposed by health plans, effectively paying health plan members to purchase Copaxone



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and leaving health plan payors to foot the bill. Second, Teva and its co-conspirators executed a product switch: when Copaxone was nearing the end of its patent exclusivity, Teva altered the dosage and coerced and persuaded patients and doctors to switch to the new dosage, which enjoyed extended patent exclusivity; this allowed Teva to avoid drug substitution laws that would have allowed or required pharmacists to fill Copaxone prescriptions with lower cost generics. Third, Teva filed numerous lawsuits and sham citizen petitions in order to delay the arrival of generic glatiramer acetate. Finally, Teva conspired with specialty pharmacies, PBMs, and doctors to cause prescriptions to be written for and filled with Copaxone instead of available, lower costs generics.

**1. Teva's Deceptive and Illegal Use of Copay Assistance.**

71. Teva conspired with a specialty pharmacy, non-profit foundations, and other entities to implement a scheme to undermine and circumvent health plan cost-sharing provisions, which would have served as a significant check on its price hikes.

**a. Health Plans Use Patient Cost-Sharing Obligation as a Check on Drug Costs.**

72. Health plans, including both private and Medicare plans, use deductibles, copayments, coinsurance, and other cost-sharing mechanisms to limit health care spending. These payments, which are referred to generally as "cost-sharing payments" or "co-pays," are amounts health plan participants must pay out-of-pocket when filling a prescription at a pharmacy. These provisions serve to better align the incentives of health plan members and health plan payors: because plan members, and not the payors, make the decision whether to purchase medications, health plans require members to share in the cost so that members do not unnecessarily cause payors to incur excessive healthcare expenses.

73. These provisions serve as a check on the price of health care. Put simply, cost-sharing mechanisms cause health plan members to limit their usage of health care, particularly as health care becomes more expensive. This, in turn, limits the health plan payor's spending. For



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example, members who have to pay 20% coinsurance would be more willing to buy a drug if it cost $100, with a $20 out-of-pocket payment, than if it cost $1000, with a $200 out-of-pocket payment. Likewise, a member is more likely to favor a generic drug for which they have to pay a $20 copayment than a brand name drug for which they have to pay a $50 copayment. These cost-share obligations provide critical incentives for members to prefer lower cost generic drugs and for drug manufacturers to price their products based on market forces, since fewer members will purchase (and thus cause their health plan payors to pay for) drugs as drug prices increase.

74. Because Teva charged $70,000 for an annual course of Copaxone, patients seeking to purchase Copaxone potentially faced thousands of dollars in annual deductible, co-insurance, and other forms of cost-sharing payments.

**b. Teva Sought to Circumvent These Price Checks.**

75. Teva knew that if participants in private health plans were exposed to high cost-sharing obligations, substantially fewer patients would have purchased Copaxone and Teva would have been forced to lower prices or lose sales.

76. Instead of lowering the price to make Copaxone affordable to health plan members, Teva instead devised a scheme to bypass these price controls by paying the cost-sharing obligations on behalf of health plan members. Because they were not exposed to the increasing price of Copaxone, these health plan members continued to purchase (and caused health plan payors to pay for) Copaxone even as the price for Copaxone skyrocketed.

77. With respect to private health plans, Teva provided "coupon" cards directly to plan members. When a member went to a pharmacy to fill a Copaxone prescription, the pharmacy would accept the coupon from the participant in lieu of collecting the participant's cost-sharing obligation, and Teva would pay the pharmacy for the value of the coupon. In other words, private health plan members would pay less for Copaxone than they would have paid for alternative MS drugs, even if Copaxone cost private health plan payors more than those alternatives.



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78. Teva offered this "coupon" service, known as "Copaxone Co-Pay Solutions," as part of its "Shared Solutions" patient-services program. Shared Solutions provided Copaxone patients with injection training and other educational services in addition to these "coupons." According to Teva, Shared Solutions was "dedicated to getting and keeping patients on" Copaxone. Teva assigned each patient a case manager who, among other things, would help them obtain copay coupons.

79. Teva was able to quickly build direct relationships with patients because Physicians who prescribed Copaxone typically submitted enrollment forms to Shared Solutions on behalf of each new Copaxone patient. Gov't Compl. ¶ 48.

80. By insulating members of private plans from price increases, Teva induced private health plan payors to pay for Copaxone despite its high cost and to continue paying for Copaxone despite cost increases.[6] A 2005 HHS OIG Advisory Bulletin explained the harm posed by these private co-pay assistance programs:

> Subsidies provided by traditional pharmaceutical manufacturer PAPs [patient assistance programs] have the practical effect of locking beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives) …. [C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions.[7]

[6] Even where plans imposed fixed-dollar copayment obligations, by paying these copay amounts on behalf of members, Teva induced private health plan payors to pay for prescriptions that might not have been purchased had participants been required to comply with their copay obligations. This is particularly true where plans impose a higher copayment obligation for brand drugs like Copaxone and a lower copay for generic versions of the same drug. In these cases, participants would be expected to favor the lower-cost generic but for Teva's intervention to effectively waive the higher brand drug copayment.

[7] HS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70626 (Nov. 22, 2005).



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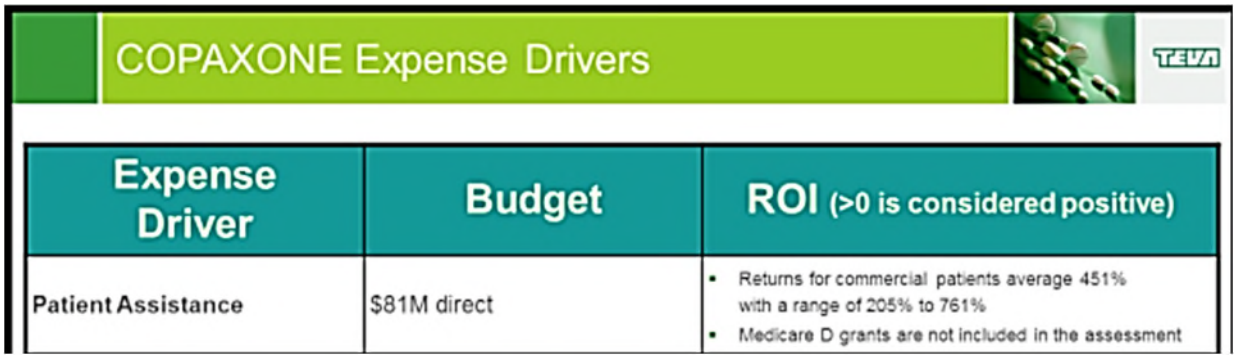
81. Teva's average return on investment on these payments to private plan members was 451%, meaning that for every $100 Teva spent on "co-pay assistance," Teva obtained $451 in profits. House Exec Summ at iii; House Report at 13. In fact, in 2014 alone, Teva collected $257.5 million in net revenue from its $54.6 million in private copay assistance expenditures. *Id.* at iv.




82. These are additional Copaxone sales that would not have occurred unless Teva either lowered its prices or relieved private plan members paid of their cost-sharing payments. Indeed, the House Committee cited Teva's 2008 Copaxone Work Plan, which "estimated that the company would spend approximately $70 million on 'Private insurance Financial Assistance' between 2008 and 2011 and that this expenditure would result in the sale of 198,930 units of Copaxone that otherwise would have been lost." House Report at 13. The House Committee described a 2017 Teva strategy presentation that "explained that the commercial co-pay programs benefited Teva's sales by ensuring that patients stayed on Copaxone over time." *Id.* at 14. Indeed, "Teva estimated that a patient on the program was 15% more likely to stay on the drug for 12 months than a patient that was not on the program." *Id.*

**c. Teva Doubled Down with an Elaborate Medicare Kickback Scheme.**

83. Although Teva's coupon program allowed it to side-step cost-sharing obligations with respect to members of private health plans, Teva knew it could not pursue this direct coupon strategy with respect to Medicare recipients and members of other federal health plans. Federal law prohibits pharmaceutical manufactures from subsidizing the co-insurance or other



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cost-sharing obligations of members of federal health plans. This obstacle was significant, as Teva documents reflect that Medicare recipients accounted for 27% of Copaxone patients. House Report at 21.

84. Moreover, this obstacle impacted not only the price Teva could charge members of Medicare plans and other federal health plans, but also the price Teva could charge members of private health plans. As explained above, a single Copaxone list price applies to all Copaxone purchases in the United States, including for Copaxone prescribed to both Medicare recipients and members of private health plans.

85. Teva thus faced the following choice: if Teva kept prices high (or continued to increase prices), it would maintain (or increase) its revenues from sales to private health plan members but lose sales to members of federal health plans; if Teva lowered prices, it would maintain sales to members of federal health plans but obtain lower revenue from sales to private health plan members.

86. But if Teva could figure out a way to further cheat the system to subsidize cost sharing obligations of Medicare recipients and other members of federal health plans, Teva could keep the single list price high for all health plan payors—private and public—without losing sales. That is precisely what Teva did.

**(i) Teva Devised an Illegal Kickback Scheme.**

87. The United States filed suit against Teva in August 2020 alleging violations of the Anti-Kickback Statute and the False Claims Act.

88. The Anti-Kickback Statute prohibits pharmaceutical manufacturers from subsidizing co-insurance and other cost-sharing obligations incurred by Medicare recipients. 42 U.S.C. § 1320a-7b(b). As the HHS OIG explained in a 2005 Advisory Bulletin, if drug



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manufacturers were permitted to pay the co-pays of Medicare recipients, they could "eliminat[e] a market safeguard against inflated prices."[8]

89. Any Medicare claim "that includes items or services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). Claims submitted to Medicare that are the result of violations of the anti-kickback statute—including claims for prescription drug purchases induced by the illegal subsidization of patient cost-sharing obligations—are *per se* false or fraudulent claims within the meaning of 31 U.S.C. § 3729(a).

90. Teva funneled over $300 million through non-profits that served as pass-through vehicles so that Teva could subsidize Medicare cost-sharing obligations for Copaxone. As the government detailed in its 59-page complaint based on its extensive review of documents, "Teva knowingly and willfully violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), by paying over $300 million to two third-party foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"), to cover the Medicare co-pay obligations of Copaxone patients. This conduct generated hundreds of millions of dollars in false claims to Medicare and a corresponding amount of revenue for Teva."[9] A copy of the government's complaint is attached hereto as Exhibit 1.

91. The government provided a detailed list of the dozens of payments Teva made to CDF and TAF, a copy of which is attached hereto as Exhibit 2. Although CDF and TAF ostensibly provided financial assistance to help patients pay co-pays for any MS drug on the market, CDF and TAF in fact conspired with Teva to ensure that the "donations" Teva made to these entities would be used to provide co-pay assistance exclusively for patients purchasing Copaxone.

[8] HHS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625-27 (Nov. 22, 2005).

[9] Complaint ¶ 1, *United States v. Teva Pharmaceuticals USA, Inc.*, No. 20-cv-11548 (D. Mass. Aug. 18, 2020), ECF No. 1 ("Gov't Compl."). Exhibits to the Gov't Compl. are referred to herein as "Gov't Exs."



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**(ii) Teva Conspired with Multiple Entities to Execute Its Illegal Kickback Scheme.**

92. To facilitate this scheme, Teva conspired with a specialty pharmacy, Advanced Care Scripts, Inc. ("ACS"), to which Teva referred Copaxone patients who either had or were eligible for Medicare coverage. ACS would then arrange for the patients to obtain co-pay assistance from CDF and TAF by sending batch files to each entity reflecting the names of Copaxone patients.

93. ACS reported to Teva the number of Copaxone patients that were referred to CDF and TAF. Gov't Exs 36-43 (e-mails from ACS to Teva reporting Copaxone patients receiving co-pay assistance from CDF and TAF). CDF and TAF also regularly provided Teva with the per-patient grant amounts. Gov't Exs 30-35.[10] Teva then used this information during its annual budgeting process to determine the amount of "donations" it paid to CDF and TAF to fund the co-pay assistance. The Government recently uncovered and disclosed detailed budget spreadsheets that reflect how Teva's "donations" to CDF and TAF were based specifically on the foundation grant amounts and Teva's projections of the cost-sharing payments faced by the Medicare recipients who were referred to CDF and TAF. Gov't Exs. 44-48. In other words, the amounts of Teva's donations each year were based on its calculation of the amount CDF and TAF would need to specifically fund Copaxone co-pay assistance for Medicare recipients. After Teva made these payments, ACS provided it with confirmation that the donations covered the Copaxone patients' costs.

94. Teva would further use information received from ACS on new patients awaiting copay assistance and would make supplemental "donations" to CDF and TAF that were earmarked to fund assistance for these new patients. The government recently disclosed a series of Teva e-mails and documents the reflect the following process: ACS would share with Teva

[10] *See also* Affidavit of Edward H. Hensley ¶ 13, *United States v. Teva Pharmaceuticals USA, Inc.*, No. 20-cv-11548 (D. Mass. Aug. 18, 2020), ECF No. 1-2 ("Hensley Aff."), attached hereto as Exhibit 3.



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how many new patients were awaiting co-pay assistance and TAF would tell Teva the average Medicare co-pay grant for a Copaxone patient at the time. Teva would then multiply those two figures and add an amount for TAF's administrative fees. Teva would then tell ACS that it intended to pay this amount to TAF. Upon receipt of this payment, TAF would re-open its co-pay fund to new applicants and ACS would provide a batch file of names of the new Copaxone patients, who were admitted to the program. *See* Gov't Compl. ¶ 90 (citing testimony of Teva's Director of Customer Resources, Denise Lynch, that this "was the normal way it was done."); Hensley Aff. ¶¶ 13-14; Gov't Exs. 42, 51-78).

95. ACS's founder, Edward Hensley, stated in a sworn affidavit that since at least 2008, he "understood that Teva was purposefully utilizing ACS and structuring its donations to CDF in a manner the essentially ensured that such donations would benefit only Copaxone patients, and not patients who had been prescribed competitor MS medications." Hensley Affidavit ¶ 3. Hensley explained that he and Teva's Director of Customer Resources, Denise Lynch, together identified CDF as a foundation that would work with their scheme, including because its "intake process … was designed to ensure that monies that a pharmaceutical manufacturer donated would flow through to that manufacturer's patients." *Id.* ¶ 5. In a 2007 email recently disclosed by the Government, Hensley instructed his ACS colleagues that "particular manufacturer funds [should] go to their own drugs as [that was] what … the intent of the project was originally." Gov't Ex. 8

96. Hensley and his co-founder of ACS, Jeff Spafford, left ACS in 2009 and founded TAF, a foundation modeled after CDF. Lynch inquired whether TAF would function similarly to CDF, and Hensley assured her and others at Teva that "TAF would provide all of the advantages that CDF did—including accepting 'batch files' of patients from a manufacturer's 'hub' or preferred specialty pharmacy, not utilizing waiting lists, and accepting donations at any time during the year." Hensley Affidavit ¶ 10. As Hensley explained, "I made sure that Ms. Lynch understood that Teva effectively would be able to use TAF as it had CDF: essentially, as a 'pass-



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through' donation vehicle to get Teva monies into the hands of Copaxone patients." *Id.* When Teva began paying TAF to provide Copaxone co-pay assistance, Hensley and TAF accepted the batch files from ACS "despite knowing that ACS had purposefully and strategically structured the batch file to benefit Copaxone patients rather than to fairly reflect ACS's population of financially needy MS patients." Hensley Affidavit ¶ 12.

97. Hensley and Spafford also founded a for-profit business called AssistRx. Although ACS continued to participate in the scheme after Hensley and Spafford departed, in February 2015, AssistRx assumed ACS's role of arranging Medicare co-pay assistance for Copaxone patients referred by Teva. In other words, by at least 2015, the same individuals—Hensley and Spafford—operated both the foundation providing the Copaxone co-pay assistance and the corporation serving as the conduit between Teva and the foundation.

98. ACS and AssistRx were rewarded for their participation in the scheme. Both entities obtained millions in service fees paid by Teva. Additionally, ACS, a specialty pharmacy, profited from additional sales of Copaxone to Medicare recipients. After ACS referred patients to CDF and TAF for co-pay assistance, ACS was the pharmacy that dispensed Copaxone to the majority of such patients.

99. Teva took steps to ensure its "donations" would be used exclusively for Copaxone and not for other MS medications. Teva timed its payments to CDF and TAF to coincide with ACS's submission of the batch files reflecting Copaxone prescriptions. Lynch told Hensley that she would not authorize donations to another co-pay foundation because it had previously "burned" her by using Teva donations to cover co-pays for other drugs. Hensley Aff. ¶ 4. Hensley further stated that "Ms. Lynch told me, in sum and substance, that Teva would only authorize a donation to a charity that could provide Teva reasonable assurance that the donation would exclusively (or at least predominately) benefit Copaxone patients." *Id.*



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**(iii) Teva Calculated Its Return on Investment**

100. The purpose of this scheme was clear: Teva subsidized the cost-sharing payments of Medicare recipients to cause Medicare to pay for Copaxone prescriptions that otherwise would not have been filled because recipients could not afford their cost-sharing payments. As the government explained, "Teva intended the payments to ensure that Copaxone patients never faced the steep prices that Teva charged for its drug, thus inducing the patients, including Medicare patients, to purchase the drug."[11] The government further explained that "Teva knew that, if it did not use CDF and TAF to subsidize Medicare patients' co-pays for Copaxone, substantially fewer patients would use Copaxone and Teva's revenue would suffer." Gov Compl. ¶ 6.

101. The government cited a statement from Katie Hiett, Teva Neuroscience's Director of Finance and Planning, to Felicia Ladin, Teva USA's Vice President of Finance, explaining that "[n]ot funding these patients has a direct and immediate impact on units [sold]." Gov Compl. ¶ 6; Gov't Ex. 13 at 1. A Teva marketing director, Mike Sheehy, sent an e-mail to his boss in December 2012 reporting that he had "provided Denise [Lynch] the direction to move forward" with additional donations in 2013 "because not doing so directly impacts the topline with existing patients." Gov't Ex. 14 at 1. In 2015, a Teva Financial analyst, Alejandro Castro, explained to Teva's VP of Finance, David Loughery, that Teva would need to pay additional "donations" of $5 and $8 million "to avoid losing an estimated 1,500 Medicare Patients." Gov't Ex. 16 at 2. Castro also quantified the impact on total revenue to Teva, noting that a reduction of $6.3 million in "donations" "may be a risk to Net Sales of approximately $5.8M *per month.*" *Id.*at 1 (emphasis added).

102. Internal documents uncovered by the House Committee further reflect that Teva expressly understood these illegal payments to the foundations to be an "investment" in future Copaxone sales. For example, Teva's 2008 Copaxone Work Plan estimated that Teva would

[11] Gov Compl. ¶ 2.



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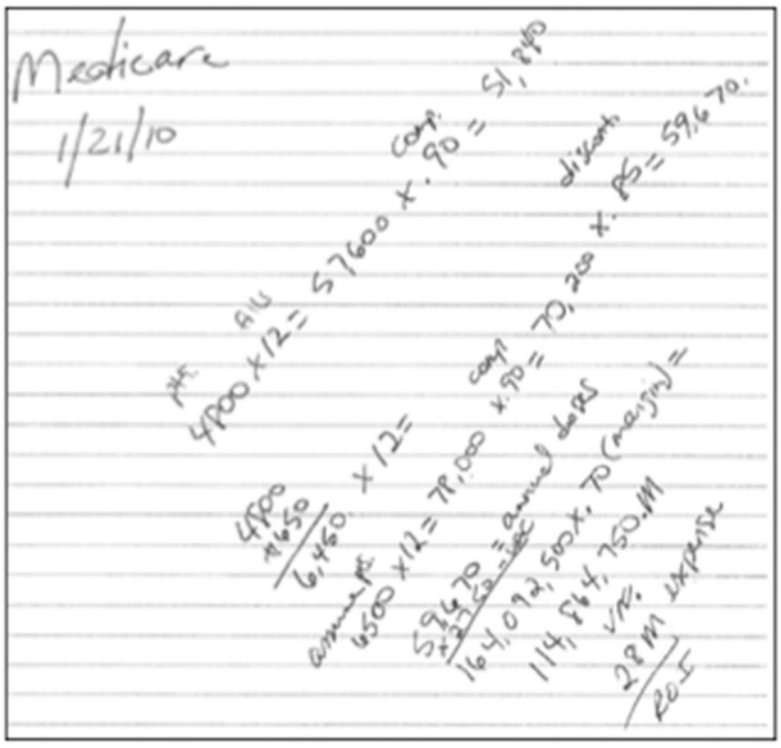
spend approximately $97 million on "Medicare Financial Assistance between 2008 and 2011, which would result in the sale of an additional 155,113 units of Copaxone worth nearly $300 million. House Report at 15. In other words, the House Committee calculated that Teva anticipated receiving a 200% return on its "investment" because the payments to the foundation would cause Medicare to purchase more than 150,000 units of Copaxone that would not have been purchased had Medicare recipients been exposed to their cost-sharing payments. *Id.*

103. The government also uncovered handwritten notes from a Teva Patient Services manager, Jenny Jackson, reflecting an "ROI" analysis of these "donations." The notes show that Teva knew in 2010 that a $28 million "expense" would result in 4,800 additional Copaxone patients generating more than $114 million in net revenue. Gov't. Compl. ¶ 65.




104. Teva raised the amounts of its "donations" in lockstep with its increases to the price of Copaxone to ensure that Medicare recipients remained insulated from their price hikes, causing Medicare to continue to pay more as the price of Copaxone skyrocketed. For example, in a November 15, 2011 e-mail, Katie Hiett forwarded Felicia Ladin a discussion of a potential



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price increase and wrote: "I discussed the need for Patient Assistance with Denise [Lynch] and incremental price increases of 9.9%/5% over planned amount of 8.9% would cause a potential patient assistance increase of $4M-$5M across all of the Copaxone patient assistance programs." Gov't Ex. 18 at 1. As Hiett later testified: "Well, if you raise the price of your product, the patient's coinsurance for out of pocket goes up as well." Gov't Compl. ¶ 62.

105. That these payments to CDF and TAF were not gratuitous donations but instead self-interested pass-through payments to Copaxone patients is further underscored by the fact that Teva's tax department wrote in a July 2013 memorandum that "[t]he payments … are made with the expectation of financial return commensurate with the amount donated and should therefore be deducted as business expense[s]." Gov't Ex. 19 at 1. Teva executives repeatedly referred to these payments as "Copaxone donations" rather than disinterested donations to help support any MS treatment. Gov't Exs. 20-22.

**(iv) Teva Management Approved the "Donations"**

106. Teva's senior executives were required to approve the "Copaxone donations" to CDF and TAF. For example, a September 23, 2015 email addressed a "request for Copaxone donations from [TAF]" and stated Teva would need "written documentation of approval at the appropriate approval authority," listing the following "Approval Authority Levels": Gov't Ex. 3 at 6.

Approval Authority Levels
$0.5M Sr. Director
$1M VP
$5M SVP (Larry Downey in the past)
$15M TEC members (Rob Koremans)
$25M CFO (Eyal Desheh)
>$25M CEO (Erez Vigodman)

107. As the House Committee explained, "[g]iven the size of Teva's donations to third-party foundations, this policy would have required them to have been approved by the company's Executive Committee, Chief Financial Officer (CFO), or Chief Executive Officer (CEO)." House Report at 16. Hensley stated in his affidavit that he "understood from [his]



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conversations with Ms. Lynch that she needed approval from Teva's senior management, including potential management in Israel, to make the larger donations and that she might not obtain that approval unless she were able to demonstrate that the donations would substantially go to Copaxone patients." Hensley Affidavit ¶ 7.

**(v) Teva Knew It Acted Unlawfully**

108. Teva knew that that it could not use CDF and TAF as pass-through vehicles to circumvent the Anti-Kickback statue. A 2005 HHS-OIG Advisory Bulletins expressly explained that although drug manufacturers may make donations to a "*bona fide* independent charity" patient assistance program, such charity "*must not function as a conduit for payments by the pharmaceutical manufacturer to patients*" and the manufacturer should not "solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." HS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625-27 (Nov. 22, 2005).

109. This Bulletin detailed the OIG's concerns with the precise type of scheme implemented by Teva:

> We are concerned that pharmaceutical manufacturers may seek improperly to maximize [its] profits by creating sham "independent" charities to operate PAPs; by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products ….

*Id.* at 70626. *See also* HHS-OIG's 2014 Supplemental Special Advisory Bulletin, Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120, 31123 (May 30, 2014) (explaining that "actions by donors to correlate their funding … with support of their own products … may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute.").

110. Teva's knowledge of these Advisory Bulletins is demonstrated by the fact that the 2005 Bulletin was expressly referenced in its original contract with CDF, Gov't Ex. 25, and the



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requirements of the Bulletin were reiterated in an OIG advisory opinion subsequently obtained by CDF.[12] Moreover, when Teva began paying TAF in 2010, Hensley sent Lynch a copy of the advisory opinion TAF had obtained from HHS-OIG earlier that year. Gov't Ex. 26. In May 2012, a Teva employee circulated a PowerPoint presentation prepared by a law firm reiterating that "the independent charity PAP must not function as a conduit for payments form the pharmaceutical manufacturer to patients." Gov't Ex. 28 at 7. And in May 2014, Hensley e-mailed Lynch a copy of the 2014 HHS-OIG bulletin. Gov't Ex. 29.

111. Notably, Hensley stated in his affidavit that after Lynch retired from Teva, she told Hensley that "she had warned Teva's senior leadership years before that Teva should 'take a reserve' to cover False Claims Act liabilities associated with Teva's donations to CDF and TAF 'in the event' that the donations came under government scrutiny." Hensley Aff. ¶ 18.

**(vi) Teva's Illegal Kickback Scheme Continued Through at Least 2018.**

112. Although the DOJ's recent suit addressed conduct occurring between 2006 and 2015, the House Committee found evidence that this conduct continued through at least 2018. House Report at 17. For example, the House Report cited an October 2016 business plan that was circulated by Teva executives that listed a $40 million "Medicare donation" as part of its Copaxone "marketing strategy." House Report at 18.

[12] HHS-OIG, Advisory Opinion 06-10 at 5, *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-10A.pdf.



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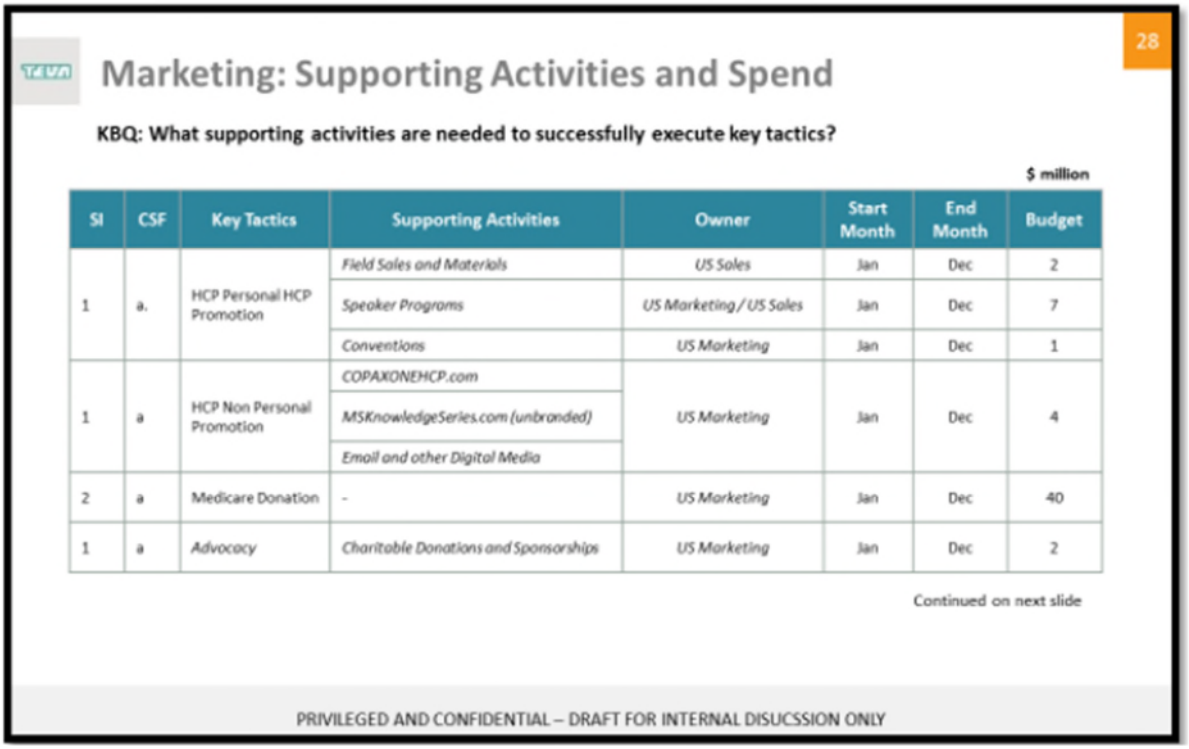

28

## Marketing: Supporting Activities and Spend

**KBQ: What supporting activities are needed to successfully execute key tactics?**

$ million

| SI | CSF | Key Tactics | Supporting Activities | Owner | Start Month | End Month | Budget |
|---|---|---|---|---|---|---|---|
| 1 | a. | HCP Personal HCP Promotion | *Field Sales and Materials* | *US Sales* | Jan | Dec | 2 |
| | | | *Speaker Programs* | *US Marketing / US Sales* | Jan | Dec | 7 |
| | | | *Conventions* | *US Marketing* | Jan | Dec | 1 |
| 1 | a | HCP Non Personal Promotion | *COPAXONEHCP.com* | *US Marketing* | Jan | Dec | 4 |
| | | | *MSKnowledgeSeries.com (unbranded)* | | | | |
| | | | *Email and other Digital Media* | | | | |
| 2 | a | Medicare Donation | - | *US Marketing* | Jan | Dec | 40 |
| 1 | a | *Advocacy* | *Charitable Donations and Sponsorships* | *US Marketing* | Jan | Dec | 2 |

Continued on next slide

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113. The House Report also cited a January 17, 2017 email and attachment documenting $38 million in 2017 "Copaxone donations" to TAF, the Patient Access Network ("PAN") Foundation's MS Fund, and HealthWell Foundation's MS Medicare Access Fund. House Report at 13 n.46. Later in 2017, Teva's VP of Finance for North American Specialty Medicine ("NASM"), David Loughery, recommended to NASM's President that Teva Neuroscience cut other "less impactful" items in its budget to facilitate an additional $5 million payment to PAN. House Report at 19. Teva Neuroscience made the requested change. *Id.* As the House Report concluded, "[t]his decision indicates that Teva's Vice President for Finance viewed the payment to PAN Foundation as an 'impactful' business investment." *Id.*

114. A 2018 draft Teva strategic document noted that eliminating Teva's "Medicare Donation" would result in the elimination of up to $261 million in Copaxone sales. House Report at 19-20. Notably, Loughery subsequently told the General Manager of Teva Neuroscience, John Hassler, to remove the analysis from the document because he was "not comfortable including



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the sales impact of the reduced donations." House Report at 20. Loughery nonetheless noted that "we believe that reducing the level of donations could mean that a significant number of patients will not be able to remain on Copaxone due to financial constraints." *Id.*

115. At the beginning of 2018, Teva's Executive Vice President for North America, Brendan O'Grady, received a presentation reporting that if Medicare recipients are unable to pay for their cost sharing obligations, they would "go off therapy, which would result in a negative impact to the brand of $201-280M." House Report at 21. The speaker's notes to the presentation noted that "Donations" were one of Teva's "[h]igh priority projects for execution." *Id.* O'Grady elsewhere commented that "we buy the patients [sic] copay down to zero." House Report 22.

116. Teva reported to the House Committee that it provided $23,286,429 in "charitable cash contributions in connection with Copaxone" in 2018. House Report at 21.

117. The House Report stated that documents "suggest that Teva's donations continued to be based on the expectation that they ultimately would be delivered to Copaxone patients." House Report at 17.

**d. The Medicare Kickback Scheme Inflated the Price of Copaxone Paid by All Health Plan Payors, Including Private Health Plan Payors.**

118. As the preceding paragraphs make clear, Teva understood that if it were exposed to market forces, fewer patients would have been able to afford Copaxone at the excessively inflated prices Teva was charging. This should have served as a check on Teva's excessive pricing and should have forced Teva to reduce prices or risk losing, by its own analyses, a significant volume of sales. Instead of lowering its prices to a level that patients could afford, Teva chose to illegally circumvent these market forces through its earmarked "donations" to subsidize participant cost-sharing obligations. This caused Medicare to continue paying for Copaxone prescriptions despite the ever-increasing cost of the drug.

119. Because a single Copaxone list price applies to all Copaxone purchases in the United States, including for Copaxone prescribed to both Medicare recipients and members of



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private health plans, Teva's illegal Medicare kickback scheme enabled Teva to increase the price paid by *all payors*, including private health plan payors like Plaintiffs. Had Teva been exposed to the price checking function of cost-sharing obligations with respect to the Medicare portion of its business, Teva would have been forced to reduce its single list price in order to avoid losing Medicare sales, and thus private health plan payors would have paid a lower price for their plan members' Copaxone prescriptions.

**2. Teva's Unfair and Deceptive Product Switching Scheme**

120. While Teva had effectively eliminated member price exposure as a check on its excessive pricing, Teva still had to contend with state laws that require or otherwise cause pharmacies to substitute lower cost generics for brand name prescriptions. Teva's patent exclusivity on Copaxone was set to expire in 2015 and Teva knew that because of state laws and price competition among pharmacies, it was likely to rapidly lose sales to generics as soon as generics became available for purchase. Rather than face these standard market forces, Teva chose an unfair and deceptive shortcut.

**a. Drug Manufacturers Use Product Switching Schemes to Avoid Generic Substitution Under Drug Substitution Laws.**

121. Because generics on average cost substantially less than their brand name counterparts, health plans may save considerable costs if patients' prescriptions are promptly converted over to the generic once it's available.

122. In most marketplaces in which products are otherwise identical, price differential alone would cause consumers to select the lower cost product. However, in the marketplace for prescription drugs in the United States, there is a disconnect between purchase price and product selection because the entity paying for product (the health plan payor) is distinct from the person choosing the product (the physician who writes the prescription). Studies repeatedly show physicians are usually unaware of the costs of pharmaceutical products. Even when physicians are aware of the relative cost, they are often insensitive to price differences because they do not



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bear the costs of the drugs being purchased. And while health plan members are partially sensitive to price by virtue of their cost-sharing obligations (in the absence of interference from coupon programs like those implemented by Teva), members are often unaware when generics exist and may not know to ask their doctor to write a prescription for a generic.

123. Every state has enacted a drug substitution or product selection law designed to fix the disconnect between the doctors who prescribe (but do not pay for) the drugs and the individuals and institutions who pay for (but do not select) the drugs. These laws allow (or in some cases require) pharmacists to substitute generic versions for a prescribed brand name drug. Even where these laws do not require substitution, pharmacists are far more price sensitive than doctors because they make greater margins on generics and compete with other pharmacies on price. Thus, the result of these drug substitution laws is that even if a doctor prescribes the more expensive brand name product, pharmacies will fill the prescription with the generic.

124. These laws permit substitution only if the generic is "AB-rated" by the FDA. For a generic drug to receive an AB-rating, it must be "therapeutically equivalent" to the brand drug. This means the generic and brand drugs must have the same: (i) active ingredient; (ii) form; (iii) dosage; (iv) strength; and (v) safety and efficacy profile.

125. Product switching is an unfair and deceptive practice that exploits these "therapeutically equivalent" rules in an effort to avoid generic substitution and prolong brand name patent exclusivity. Product switching occurs when a brand drug company with a product nearing the end of its patent exclusivity introduces a modest reformulation of the brand drug before it faces generic substitution. The reformulation alters the form, dosage, or strength of the brand drug such that the reformulated version is not "therapeutically equivalent" to the original drug. As such, generic versions of the original brand drug cannot be substituted for the reformulated brand drug under drug substitution laws. And because the reformulated version of the drug enjoys a new period of patent exclusivity, there would be no "therapeutically



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equivalent" generic, and thus no threat of generic substitution, until the end of the patent exclusivity on the reformulated brand drug.

126. Product switching is particularly problematic where, as here, the brand drug company persuades or coerces patients to convert to the reformulated version of the brand drug before the patent exclusivity on the original brand drug expires. Drug companies like Teva know that if the reformulated version is delayed until after patients are switched over to lower-cost generics under drug substitution laws, patients would be inclined to remain on the lower cost generics rather than switching again to a higher-cost reformulation of the brand drug. But if the drug company can persuade or coerce patients into switching to a new version of its brand drug while the original brand drug still enjoys patent exclusivity, patients will not have known the benefit of the lower cost generic and will have begun the reformulated drug before drug substitution laws kick in.

127. As the European Commission explained in its detailed inquiry into the pharmaceutical industry,

> Timing the launch of a follow-on product is crucial for originator companies. If cheaper, generic versions of the first product come on the market before or simultaneously with the switch to the follow-on product, the originator company may incur considerable value losses both in terms of smaller volumes and reduced prices. Therefore, it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity.[13]

128. It is well known that after doctors have switched patients to the reformulated product, they are unlikely to switch back and prescribe the original product. And because the reformulated drug is not "therapeutically equivalent" to the generic versions of the original brand drug, pharmacists cannot replace prescriptions for the reformulated drug with generic versions of the original drug. As one expert explained, "[i]f the brand successfully switches the market to the

[13] Pharmaceutical Sector Inquiry Final Report, European Comm'n, ¶ 1010 (2009), https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.



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reformulated product before the generic enters, the generic entry is of no practical significance: there are few or no prescriptions for the original product for which the generic can be substituted."[14]

**b. Teva's Copaxone Product Switch**

129. The original version of Copaxone came in a 20mg/ml dosage that was to be taken once daily. Patent exclusivity on 20mg Copaxone was set to expire in 2015.

In 2014 Teva introduced a reformulated 40mg/ml version of Copaxone that was to be taken three times weekly. The FDA granted approval for Teva to market the new dose on January 28, 2014, and Teva released 40mg Copaxone the following day. This was almost 18 months before Sandoz launched Glatopa, the first generic 20mg version of glatiramer acetate.[15]

130. Teva engaged in a multi-pronged campaign to persuade and coerce doctors, pharmacies, and patients to switch from 20mg Copaxone to 40mg Copaxone before Glatopa or other 20mg generics became available for purchase.


131. First, Teva manipulated the pricing of both versions of Copaxone to induce patients to switch to 40mg Copaxone. As the House Committee found, Teva initially priced 40mg Copaxone as "slightly less expensive per week of treatment than Copaxone 20mg/ml." House Report at 30. Shortly thereafter, Teva increased the price of 20mg Copaxone by 9.8%. *Id.* The House Committee found that this price increase was "part of Teva's 2014 strategic plan,

[14] Michael A. Carrier, et al., "Product Hopping: A New Framework," 92 Notre Dame L. Rev. 167, 176 (Nov. 2016), https://scholarship.law.nd.edu/ndlr/vol92/iss1/4.

[15] Sandoz, *Press Release: Sandoz Announces U.S. Launch of Glatopa, the First Generic Competitor to Copaxone 20 mg* (June 19, 2015), http://www.us.sandoz.com/news/media-releases/sandoz-announces-us-launch-glatopatm-first-generic-competitor-copaxoner-20mg.



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which emphasized that one method to 'Divert to 40' was to 'raise 20mg price.'" *Id.* Teva documents uncovered by the House Committee expressly describe the scheme as a "generic defense strategy" designed to create "rapid transition of COPAXONE 20mg to 40mg prior to expected generics in mid-2014." *Id.*

132. Second, Teva pressured PBMs to make 40mg Copaxone available to participants of health plans. Teva threatened PBMs that it would stop paying the PBMs rebates on 20mg Copaxone unless the PBMs made 40mg Copaxone available on their formularies. House Report at 31. On at least one occasion, internal Teva emails indicate that Teva followed through on the threat, eliminating Copaxone rebates for at least one PBM that failed to add 40mg Copaxone to its formulary. *Id.* This pressure worked: the following year, the PBM added 40mg Copaxone to its formulary. *Id.*

133. Third, Teva colluded with PBMs to implement a so-called "Copaxone conversion initiative." Teva entered into contracts with one or more PBMs under which the PBM(s) "committed to converting Copaxone 20mg patients over to Copaxone 40mg with their physician members." House Report at 32. Under this program, the PBM(s) would "contact[] the prescribers via fax and phone to make them aware of which patients are still on Copaxone 20mg and encourage them to switch these patients to Copaxone 40mg." *Id.*

134. Fourth, Teva itself directly targeted physicians with an intense outreach campaign through its sales force. Members of Teva's sales force contacted physicians to encourage them to (i) "initiate and upgrade any remaining patients to TIW [three times weekly] Copaxone 40mg"; (ii) "switch patients to TIW Copaxone 40mg if payers force to generic GA for daily dose"; (iii) "Prescribe Copaxone DAW [Dispense as Written] for new and existing patients"; and (iv) "Encourage their patients to accept only branded Copaxone." House Report at 32. And Teva created financial incentives for its sales force to execute this plan, making their bonuses dependent entirely on the sales of 40mg Copaxone. *Id.*



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135. Finally, the House Committee found that Teva at least "explored" a plan to coerce patients to switch to 40mg Copaxone by discontinuing copay assistance programs for the 20mg dosage, "which would make it more expensive for patients to remain on the lower dose of the medication." House Report at 30-31. The House uncovered a Teva document describing "Marketing: Deliverables," which indicated that the discontinuation of these "20mg Financial Programs (Patient Services)" was "in process" with a start date of August 14, 2014 and a completion date of December 14, 2014. House Report at 31.

136. These efforts to convert patients from 20mg Copaxone to 40mg Copaxone proved successful. Teva CEO Erez Vigodman boasted that by December 2015, Teva converted 76.9% of patients to 40mg and limited generic 20mg market share to 19.3%. House Report at 33.

**c. Teva's Clear Objective Was to Avoid Generic Substitution**

137. Teva's objective was clear: Teva introduced a modest reformulation of Copaxone and pushed its patients to the new version as part of a "generic defense strategy" to avoid generic substitution that otherwise would have occurred under drug substitution laws, thus allowing Teva to continue charging ever increasing and excessive prices for Copaxone without losing sales. An outside consultant to Teva characterized the strategy as follows: prior to the launch of the first 20mg generic, Glatopa, "Teva released and promoted a long-acting Copaxone 40MG, effectively pushing existing and new patients to the branded 40MG and minimizing generic substitution." House Report at 34. In June 2016—almost a year after the 20mg generic Glatopa had been on the market—an internal presentation from Teva's General Manager of Neuroscience bragged that "[t]he strategy of switching patients to 40mg version of the medicine is continuing to be successful and reduce the impact of generic competition." House Report at 33-34.

138. Teva's product switch was the result of more than a decade of planning. In 2002 Teva senior executives began holding meetings on Copaxone "Life Cycle Management," which, as the House Committee explained, is "an industry term for the use of incremental research to extend a profitable drug's market monopoly." House Report at 24. Teva Executives emphasized



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to Teva's Board of Directors that one objective of life cycle management was to "Minimize the risk of generic competition." *Id.*

139. In June 2009, Teva's executives prepared a presentation on "Copaxone LCM—Mid Term Initiatives" for then-CEO Shlomo Yanai. House Report at 27. This presentation described "a need to '[d]evelop a low frequency formulation of GA' to ensure the competitiveness of Copaxone in the future. …'" *Id.* Incredibly, this presentation conceded there was "' [n]o supporting data for the selected dose or dosing regimen" and that "overall, the data available to date do not support going to higher doses.'" *Id.* at 28.

140. Internal documents show that Teva originally sought to introduce the new 40mg/ml dose as a "more effective" daily dose to replace the existing 20 mgl/ml daily dose. But after Teva's internal study (called Forte) showed there was no difference in efficacy between the two doses, Teva documents posed the question: "How do we justify the use of higher doses after Forte?" House Report at 25-26. In other words, the higher dosage was a solution in search of a pretextual problem. Teva's response was to explore "higher doses in [a] less frequent dose regimen." *Id.* at 26.

141. Although Teva has attempted to justify the three-times weekly dosage as more convenient to patients, the House Committee cited a statement from a Teva executive conceding that "every other day over once daily does not represent a significant improvement in convenience." House Report at 25. When Teva nonetheless sought to research a shift to a three-times weekly dosage, one of Teva's scientists in its Innovative Research and Development (IR&D) group expressed that IR&D management were "'strongly against' Teva's study into the less-frequent dosing of Copaxone 'since it has no scientific rationale/value.'" House Report at 27. This scientist further noted that Teva's life cycle management team agrees, but nonetheless they "think that such a study has its business value." *Id.*

142. The House Committee further found that Teva's "[i]nternal discussions in November 2009 undermine Teva's claims that it launched the 40mg/ml three times per week to



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benefit patients and not to protect the Copaxone franchise." House Report at 28. As the House Report explained:

> That month, Teva decided against doing research on the efficacy of administering Copaxone 40 mg/ml once per week—which presumably would have been even more convenient for patients. Teva's then-CEO Shlomo Yanai feared that such research would lead patients to take two injections of a cheaper generic version of Copaxone 20 mg/ml once per week rather than Teva's Copaxone 40 mg/ml.
>
> *Id.*

143. Another internal Teva document explained that the new dosage would provide Teva with a "Patent protection extension" and would serve as a "Barrier to Generic entrance." House Report at 28-29. This document noted that the new dose provided "[n]o major advantage on GA 20mg." *Id.*

144. Despite Teva's true motivations to avoid generic substitution and its internal concessions that 40mg Copaxone was not "a significant improvement in convenience," Teva misled the public by marketing 40mg Copaxone as "a significant advancement for patients."[16] Moreover, despite Teva's extensive efforts to reverse engineer a justification for altering the dosage of Copaxone, Larry Downey, Teva's President for North America Specialty Medicines, misleadingly stated:

> We have progressively invested in the innovation of COPAXONE® in an effort to understand the needs and to ease the burden of patients who live with relapsing forms of MS every day. Today we are proud to continue to deliver on that investment by offering the freedom to dose three-times-a-week with COPAXONE® 40 mg/mL.[17]

145. Ultimately, Teva's product switching strategy allowed Teva to effectively avoid generic competition until at least 2017, when generic 40mg glatiramer acetate finally entered the market after Teva's patent on 40mg Copaxone was invalidated by a federal court.

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[16] *Teva Announces U.S. FDA Approval of Three-Times-a-Week COPAXONE® (glatiramer acetate injection) 40mg/mL*, Teva Pharmaceutical Industries, Ltd. (January 29, 2014), https://www.tevapharm.com/news-and-media/latest-news/teva-announces-u.s.-fda-approval-of-three-times-a-week-copaxone-glatiramer-acetate-injection-40mgml/.

[17] *Id.*



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**d. Teva's Product Switch Was Extremely Costly**

146. Product switching is extremely costly to the United States healthcare system, as health plans continue to pay for higher cost brand drugs rather than lower cost generics. And because the reformulated brand drug does not face generic competition, there is no incentive for the brand manufacturer to lower prices. A September 2020 study of just five product switches found that the practice resulted in excess healthcare spending of $4.7 billion annually.

147. The cost of Teva's product switch is no different. A 2020 study by researchers from Harvard University found that by delaying generic competition by two and a half years, Teva's product switch resulted in excess spending by payors in the U.S. health care system of between $4.3 and $6.5 billion.[18] The House Committee reported that "[b]y shifting patients from Copaxone 20 mg/ml to 40mg/ml, Teva maintained more than $3 billion in annual net revenue from 2015 to 2017." House Report at 35.

**3. Sham Litigation and Citizen Petitions**

148. As part of its effort to avoid generic competition and to delay generic competition until Teva could convert patients to 40mg Copaxone, Teva engaged in a decades-long campaign of filing patent litigation and citizen petitions challenging generic versions of glatiramer acetate.

149. Teva initiated almost as dozen patent lawsuits seeking to enforce more than a dozen patents against companies who sought to introduce generic versions of glatiramer acetate.

150. Teva also used the FDA's citizen petition process to delay the entry of generics. A citizen petition is intended for members of the public to raise safety concerns with the FDA. But, in this case, Teva was using citizen petition to continue blocking generics from competing with Copaxone. Such petitions by brand drug manufacturers are "almost never granted," but they

[18] Benjamin N. Rome, et al., *US Spending Associated with Transition from Daily to 3-Times-Weekly Glatiramer Acetate*, Journal of the American Medical Association Internal Medicine (July 20, 2020), https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2768653.



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typically have the effect, absent some intervening event, of impeding market entry efforts of a generic for about 150 days, while the FDA considers the petition.[19]

151. As one leading scholar Michael Carrier of Rutgers Law School has explained: "Brand firms' filing of citizen petitions with the U.S. Food and Drug Administration ("FDA") has almost entirely slipped beneath the radar. In theory, citizen petitions could raise concerns that a drug is unsafe. But in practice they bear a dangerous potential to extend brand monopolies by delaying approval of generics, at a potential cost of millions of dollars per day."[20]

152. Citizen petitions cost little for the companies that file them. Consisting of boilerplate arguments, generally involving scientific data regarding a drug's manufacturing process, they are easy to file. Nor are there any consequences to filing frivolous petitions.[21]

153. Between 2008 and 2015, Teva filed an astonishing eight Citizen Petitions with the FDA, which sought to block the approval of generic glatiramer acetate products.[22] Teva's first petition sought to have the FDA prevent any generic drug company from relying on the two abbreviated pathways commonly used for obtaining generic approval: the ANDA and the

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[19] Michael A. Carrier, et al., "Citizen Petitions: Long, Late-Filed, and At-Last Denied," 66 AM. U. L. REV. 305, 308; 347 (Dec. 2016), https://digitalcommons.wcl.american.edu/cgi/viewcontent. cgi?article=1956&context=aulr&httpsredir=1&referer=.

[20] *Id.* at 307.

[21] Carrier & Wander, "Citizens Petitions: An Empirical Study", 34 CARDOZA L. REV. 249, 279 (Oct. 2012) (citing The Generic Drug Maze: Speeding Access to Affordable, LifeSaving Drugs: Hearing Before the S. Spec. Comm. on Aging, 109th Cong. 6 (2006), https://www.aging.senate.gov/imo/media/doc/hr161hb.pdf).

[22] Teva Neuroscience, Inc. Citizen Petition, No. FDA-2008-P-0529 (Sept. 26, 2008), Regulations.gov, https://www.regulations.gov/document/FDA-2008-P-0529-0001 (follow "Download" hyperlink); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2009-P-0555 (Nov. 13, 2009), Regulations.gov, https://www.regulations.gov/document/FDA-2009-P-0555-0001 (follow "Download" hyperlink); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2010-P-0642 (Dec. 10, 2010), Regulations.gov, https://www.regulations.gov/document/FDA-2010-P-0642-0001 (follow "Download" hyperlink); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2012-P-0555 (June 4, 2012), Regulations.gov, https://www.regulations.gov/document/FDA-2012-P-0555-0001 (follow "Download" hyperlink for Teva Pharmaceuticals Ltd Citizen Petition); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2013-P-1128 (Sept. 12, 2013), https://www.regulations.gov/document/FDA-2013-P-1128-0001 (follow "Download" hyperlink for Teva Pharmaceuticals Ltd Citizen Petition); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2013-P-1641 (Dec. 5, 2013), Regulations.gov, https://www.regulations.gov/document/FDA-2013-P-1641-0001 (follow "Download" hyperlink for Citizen Petition from TEVA Pharmaceuticals); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2014-P-0933 (July 2, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2014-P-0933-0001 (follow "Download" hyperlink for Citizen Petition From Teva Neuroscience Inc Redacted); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2015-P-1050 (Mar. 31, 2015), Regulations.gov, https://www.regulations.gov/document/FDA-2015-P-1050-0001 (follow "Download" hyperlink).



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505(b)(2). Both of these expedited procedures allow applicants to rely on the FDA's prior findings that the referenced drug, in this case Copaxone, is safe and effective. If this petition had been granted, it would have delayed the process for obtaining generic approval. Teva's first petition further requested that no generic, even if approved, should be given an AB rating, meaning no generic could be substituted for Copaxone under drug substitution laws.

154. Teva's subsequent petitions made similar arguments and sought to delay generic approvals and make the process for obtaining such approvals more burdensome, including by imposing requirements to conduct clinical studies and switching studies that went well beyond the traditional FDCA approval requirements for generic drugs. Professor Carrier discussed Teva's use of serial citizen petitions, calling it a "particularly glaring example of a company's aggressive use of the citizen petition process."[23]

155. Every one of Teva's petitions was denied or withdrawn.[24]

156. Another concern with citizen petitions filed by brand drug companies is the proximity between when the FDA resolves the petition and when it approves the generic ANDA. "The concern in this scenario is that generic entry could be delayed because the FDA does not

[23] Michael A. Carrier, et al., "Citizen Petitions: Long, Late-Filed, and At-Last Denied," 66 AM. U. L. REV. 305, 345 (Dec. 2016), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulr&httpsredir=1&referer=.

[24] FDA Denial of Citizen Petition, No. FDA-2008-P-0529 (Mar. 25, 2009), Regulations.gov, https://www.regulations.gov/document/FDA-2008-P-0529-0007 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2009-P-0555 (May 11, 2010), Regulations.gov, https://www.regulations.gov/document/FDA-2009-P-0555-0007 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2010-P-0642 (June 8, 2011), Regulations.gov, https://www.regulations.gov/document/FDA-2010-P-0642-0008 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2012-P-0555 (Nov. 12, 2012), Regulations.gov, https://www.regulations.gov/document/FDA-2012-P-0555-0005 (follow "Download" hyperlink); Teva Neuroscience, Inc. Withdrawal of Citizen Petition, No. FDA-2013-P-1128 (Jan. 3, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2013-P-1128-0005 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2013-P-1641 (May 2, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2013-P-1641-0009 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2014-P-0933 (Nov. 26, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2014-P-0933-0021 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2015-P-1050 (Apr. 16, 2015), Regulations.gov, https://www.regulations.gov/document/FDA-2015-P-1050-0012 (follow "Download" hyperlink).



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approve the ANDA until it resolves the citizen petition."[25] The FDA rejected Teva's final citizen petition, which challenged Sandoz's generic application, on the same day the FDA approved Sandoz's ANDA for 20mg Glatopa,[26] further raising concerns that Teva's citizen petition delayed the approval of Sandoz's ANDA.

157. Teva's efforts did not end when 20mg generic forms of glatiramer acetate entered the market. Rather, Teva fought to protect its patents on 40mg Copaxone to bar generic substitution and ensure the continued effectiveness of its product switching scheme. Teva filed at least five lawsuits for patent infringement against generic drug manufacturers who had submitted ANDAs for approval to market and sell 40mg glatiramer acetate prior to the expiration of Teva's patents on 40mg Copaxone. After a seven-day bench trial, the district court invalidated the patents on 40mg Copaxone because the change from the 20mg to 40mg formulation was too "obvious" under 35 U.S.C. § 103(a), which at the time provided that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *See In Re: Copaxone Consol. Cases*, 906 F.3d 1013, 1024 (Fed. Cir. 2018) (affirming the invalidation of Teva's 40mg Copaxone patents).

158. In February 2020, Teva engaged in yet another attempt to circumvent the drug substitution laws and thus avoid generic competition. Teva sought to have the FDA reclassify Copaxone as a "biological product" under the Public Health Service Act ("PHSA"), 42 U.S.C. § 201 *et seq.*, rather than as a "drug" under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.* Teva claimed this change was made necessary by the Biologics Price

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[25] Michael A. Carrier, et al., "Citizen Petitions: Long, Late-Filed, and At-Last Denied," 66 AM. U. L. REV. 305, 341 (Dec. 2016).

[26] Compare GLATOPA, DRUGS @ FDA, U.S. Food and Drug Administration, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090218 (toggle "Approval Date(s)…" dropdown tab for the approval date; toggle "Therapeutics Equivalents…" dropdown tab for reference to COPAXONE) (showing Sandoz-sponsored ANDA 090218, the only approved generic referencing COPAXONE, approved on April 16, 2015), with Teva Neuroscience, Inc. Citizen Petition, No. FDA-2015-P-1050-0001, at 2–4 (Apr. 1, 2015), Regulations.gov, https://www.regulations.gov/document/FDA-2015-P-1050-0001 (follow "Download" hyperlink) (denied on April 16, 2015, supra note 24).



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Competition and Innovation Act of 2009 ("BPCIA") and subsequent amendments, which altered the definition of "biological product" to include "proteins" and other analogous therapeutic products and required such products to be reclassified by March 23, 2020.

159. Teva sought this reclassification because it would have allowed Copaxone to avoid generic substitution under state drug substitution laws. Although all states allow (and in some cases require) pharmacists to substitute generic versions for a prescribed brand name drug, the same is not the cases for "biological products." Some states do not allow any substitution of biological products. Those that do allow substitution of biological products require the generic to have satisfied the FDA's heightened "interchangeability" requirement, which applies to biological products but not to drugs. 42 U.S.C. § 262(h)(3), (k)(3)(A)(ii), (k)(4).

160. Teva knew that no generic had been declared "interchangeable" with Copaxone. Teva also knew that the FDA's process of evaluating interchangeability was onerous because, among other things, the FDA generally requires a clinical "switching study" to evaluate whether switching between the brand and the generic is risker than using only a single product.

161. Teva thus knew that, at a minimum, reclassification of Copaxone as a "biological product" would delay any further generic substitution and possibly end it altogether. As Teva USA's Vice President for Specialty Product Marketing, Dalton Tomlinson, stated in a sworn declaration,

> [I]f COPAXONE were deemed to be licensed as a biological product rather than approved as a drug, then in nearly all cases, a prescription for "COPAXONE" would be filled with Teva's product, rather than the generic that is currently substituted. … Accordingly, because prescriptions written for "COPAXONE" would be filled with Teva's product, Teva's market share would increase unless prescribers' behavior changed significantly.

Declaration of Dalton Tomlinson at ¶¶ 15-16, *Teva Pharm. USA, Inc. et al. v. U.S. Food and Drug Admin. et al.*, 1:20-cv-00808-BAH, (D.D.C. July 16, 2020) ECF No. 41-2.

162. After the FDA refused to reclassify Copaxone, Teva filed suit against the FDA. In dismissing Teva's claims, Chief Judge Beryl A. Howell of the District of Columbia District



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referred to Teva's conduct as "yet another effort to stifle Copaxone competitors." Memorandum Opinion at 1, *Teva Pharm. USA, Inc. et al. v. U.S. Food and Drug Admin. et al.*, 1:20-cv-00808-BAH, (D.D.C. Dec. 31, 2020) ECF No. 54.

**4. Additional Manipulative Conduct**

163. After Mylan introduced a lower priced generic version of Copaxone 40mg/ml in October 2017, Teva pursued several additional, manipulative tactics to induce private health plan payors to continue paying for Copaxone. The House Committee found that "Teva contracted with specialty pharmacies and pharmacy benefit managers to limit generic substitution." House Exec Summ at iv. The House Committee also found that "Teva lobbied doctors to write prescriptions for Copaxone that prohibited generic substitution" (i.e. "dispense as written") and "used its patient programs to convince patients to remain on the more expensive brand name version of the drug." *Id.*

**a. Teva's "House Brand" Strategy**

164. One of the tactics employed by Teva to impede health plan members from accessing lower cost generics was a "Brand Over Generic" or so-called "House Brand" contracting strategy. As the name implies, Teva's "Brand Over Generic" strategy involved contracting with PBMs and specialty pharmacies to make Copaxone 40 mg/ml the drug that was covered by health plans and dispensed to health plan members, as opposed to a cheaper generic version of glatiramer acetate—thereby inverting the usual course under generic substitution laws.

165. When Mylan received approval to market its generic version of glatiramer acetate, Teva quickly sought to implement its "House Brand" strategy. Documents from the House Report reflect that, on October 26, 2017 (the same month as Mylan's approval), the General Manager of Teva Neuroscience, John Hassler, notified Teva CNS CEO Larry Downey: "'Two weeks post generic approval, the team has already had early success in achieving key Brand Over Generic goals,'" and that "'45% of units have been targeted via House Brand Agreements.'" House Report at 37.



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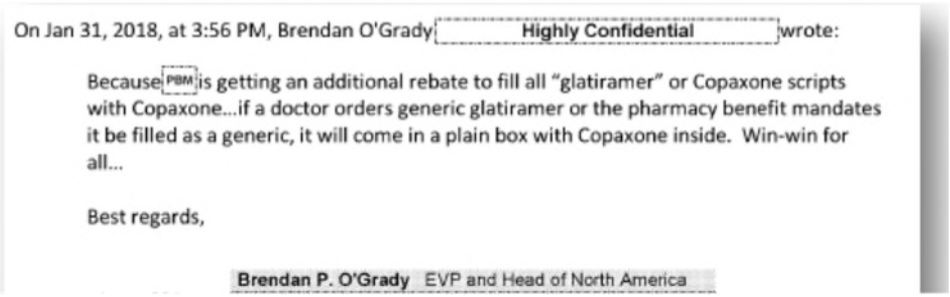
166. With respect to certain PBMs, Teva executed its "House Brand" strategy through contracts that restricted generic access at the formulary level. Internal Teva documents reflected that "2 of the House Brand target accounts will be executed at the formulary level. Blocking the generic via formulary restriction." *Id.*

167. With respect to specialty pharmacies, Teva contracted with certain pharmacies so that prescriptions for glatiramer acetate would be filled with brand, regardless of whether a generic was prescribed. Internal Teva documents reflected that "2 of the House Brand target accounts will be executed at the specialty pharmacy level. Pharmacy will fill brand regardless if prescribed as generic." *Id.*

168. A series of emails uncovered by the House Committee showed how the "House Brand" strategy was effective at preventing health plan members from receiving lower cost generics. In response to employee questions regarding the effects on Teva should an insurer place 40mg Copaxone on a more restrictive formulary tier, Teva's Executive Vice President for North America, Brendan O'Grady, responded that the insurer's decision would have "almost zero impact on actual prescriptions" because the insurer's members would have their prescriptions filled by a specialty pharmacy that would give members Copaxone instead of the generic:


On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone...if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all...

Best regards,

Brendan P. O'Grady EVP and Head of North America

House Report at 37-38. Thus even if a patient wanted the generic, a doctor prescribed the generic, or an insurer sought to favor the generic, Teva's conduct sought to ensure that pharmacies would fill all prescriptions with Copaxone, even if it meant putting Copaxone in a plain box.



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169. The House Report further noted: "Earlier in the email, a Teva executive had warned subordinates that the contract with [specialty pharmacy] should 'not be formally shared with the sales team' because of the 'confidential nature of the [specialty pharmacy] House Brand strategy." House Report at 38.

170. The House concluded that "[b]y April 2018, Teva had entered into House Brand Agreements with a number of PBMs for Medicare and commercial patients. Some of these agreements blocked generics from formularies while others replaced generics at the specialty pharmacy." House Report at 39.

**b. Dispense As Written**

171. Manipulation of physician prescribing decisions plays into another complexity of the pharmacy market, as described by Professor Carrier:

> Unlike other markets, "the consumer who pays does not choose, and the physician who chooses does not pay." This disconnect has created a gap that can be exploited. Brand firms can convince doctors to prescribe expensive drugs even if equally effective cheaper drugs are available. In fact, brands have done so through an array of activity that includes samples, mailing, detailing (sales calls to doctor's offices), sponsored continuing medical education programs, and advertising in medial and medical journals.[27]

172. As described *supra* ¶¶ 123-124, state generic substitution laws allow—or require—pharmacists to fill prescriptions for branded pharmaceuticals with equivalent generic pharmaceuticals. The exception is for prescriptions with the notation "Dispense as Written" or "DAW," by which the prescribing physician can prohibit generic substitution.

173. In response to generic competition, Teva began a campaign to convince doctors to write prescriptions for Copaxone as DAW to stop generic substitution. In internal Teva strategy documents reviewed by the House Committee, the DAW campaign was identified as a key component of Teva's strategy to prevent health plan members from receiving lower cost

[27] Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 Santa Clara L. Rev. 615, 616 (2020) (quoting Bureau of Consumer Protection, Drug Product Selection: Staff Report to the F.T.C.2 (Jan. 1979)).



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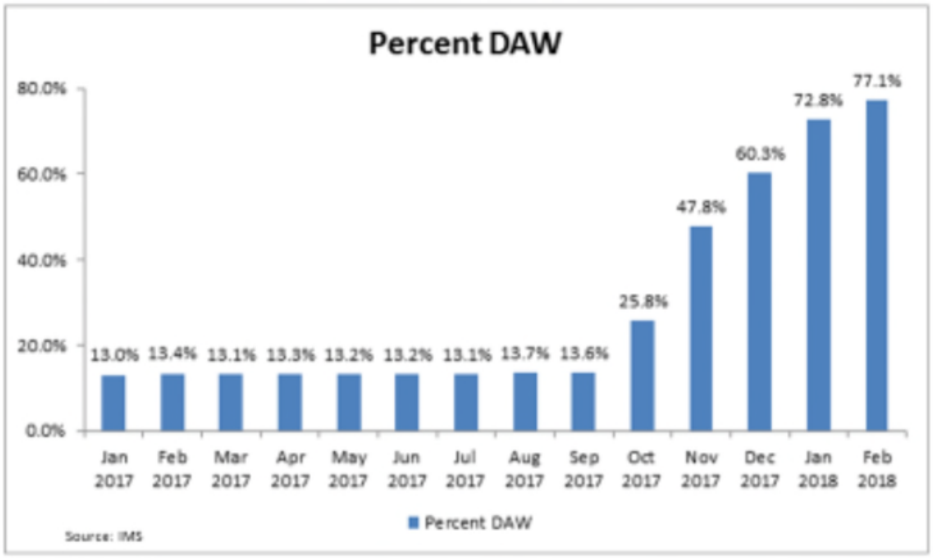
generics. Teva encouraged doctors to "'Prescribe Copaxone DAW for new and existing patients.'" House Report at 39. The House Committee also found that Teva executives "touted their '[a]bility to produce current 40mg patient lists for HCP [Health Care Professional] offices' to 'proactively' write DAW on prescriptions." *Id.* at 40.

174. Teva's DAW campaign was highly successful. "By February 2018, 77% of Copaxone prescriptions were written with the 'DAW' notation." *Id.*




*Id.*

175. In August 2018, Brendan O'Grady encouraged his team to "Keep up pressure on Copaxone and maximize office calls," noting that "the DAW campaign combined with the legacy and house brand access strategy has paid great dividends." House Report at 40. O'Grady set a goal of $1.5 billion in net Copaxone revenue for 2018. *Id.* Teva ultimately exceeded this goal, collecting $1.6 billion in net Copaxone revenue for the year despite the availability of lower costs generics. *Id.* at 41.

**c. Shared Solutions**

176. Teva also used its patient assistance program, known as Shared Solutions, to convince patients to remain on the more expensive brand version of the drug.



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177. The Shared Solutions program offers a variety of services to Copaxone users, including providing free injection devices, free injection training, and assistance with obtaining insurance coverage.

178. As noted above, Teva was able to quickly enroll patients in Shared Solutions because when Physicians prescribed Copaxone, they would typically submit enrollment forms to Shared Solutions on behalf of each new Copaxone patient. Gov't Compl. ¶ 48.

179. Teva used this program to persuade members of private health plans to ask their doctors to write Copaxone prescriptions with the DAW notation, further reinforcing Teva's DAW program and undermining drug substitution laws. Internal Teva documents reflect that through this program, Teva sent "'[e]mails to all patients with DAW messaging.'" House Report. at 23. Another Teva document from August 2018 emphasized the need to "reinforce DAW on every call" and use "Marketing driven patient programs and telecons to supplement patient education/support." *Id.* at 23-24.

180. Teva also pressed the DAW campaign through its "Shared Solutions" program to great success. The House Report noted: "According to an internal analysis in August 2017, DAW was written on 87% of Copaxone 40mg/ml prescriptions requested through Teva's 'Shared Solutions Copaxone Prescription Service Request form.'" House Report at 39.

## V. EQUITABLE TOLLING, DISCOVERY RULE, AND FRAUDULENT CONCEALMENT

181. At all times relevant to this Complaint, Teva took active steps to conceal its unlawful activities, including through the combination or conspiracy alleged herein. For example, and without limitation, Teva and its co-conspirators concealed their efforts to defraud Medicare by funneling sham "donations" through non-profit foundations. By paying pharmacies to not collect cost-sharing obligations from private health plan members through their "co-pay" assistance program and by causing pharmacies to report the full, undiscounted drug price when submitting claims to PBMs and private health plans, Teva and its co-conspirators concealed the



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extent to which they induced private plan payors to pay for Copaxone. Teva misrepresented why it introduced 40mg Copaxone and otherwise concealed its true motive of avoiding generic substitution, and further concealed its efforts to collude with PBMs and physicians to convert participants to 40mg Copaxone before generic versions of 20mg glatiramer acetate hit the market. Teva also concealed its efforts to conspire with PBMs to make Copaxone the exclusive or prioritized drug on formularies and to conspire with specialty pharmacies to have generic prescriptions filled with Copaxone.

182. **Discovery Rule:** Plaintiffs and the members of the Class had no knowledge of the combination or conspiracy alleged herein, or of facts sufficient to place them on inquiry notice of the claims set forth herein, until August and September of 2020, when the government filed its complaint related to Teva's scheme to defraud Medicare and the House Committee released its report.

183. Plaintiffs and members of the Class are private health plan payors who did not interact with Teva and had no means from which they could have discovered the combination and conspiracy described in this Complaint before August and September of 2020.

184. Information in the public domain was insufficient to place Plaintiffs and members of the Class on inquiry notice of Defendants' unlawful, unfair, and deceptive activities, including the combination or conspiracy alleged herein, prior August and September of 2020. Further, Plaintiffs and the members of the Class had no means of obtaining any facts or information concerning the Defendants' unlawful, unfair, and deceptive activities alleged herein, all of which were purposefully concealed by Defendants.

185. For these reasons, any statutes of limitations applicable to the claims of Plaintiffs and the Class did not begin to run and have been tolled until the Government filed its complaint in August 2020 and the House Committee released its report in September 2020.



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186. **Fraudulent Concealment:** The statutes of limitation were further tolled by the doctrine of fraudulent concealment. Teva actively concealed the existence of its illegal scheme, including through false or misleading representations.

187. Teva concealed its illegal payments to Medicare recipients by funneling them through CDF and TAF. Teva represented that it was making disinterested "donations" to CDF and TAF to help patients afford any and all MS prescriptions when, in fact, it took concerted efforts to ensure that its "donations" would be utilized exclusively for Copaxone patients. Teva concealed the illegal communication of data and information necessarily to calculate the precise amounts of its contributions by using ACS and AssistRx as conduits for information. CDF and TAF likewise held themselves out as bona fide charities providing assistance for all MS prescriptions when, in fact, they were serving as "pass-through donation vehicle[s]" to funnel money from Teva to Copaxone patients. These efforts, in combination with Teva's knowledge that its kickback scheme violated the law, demonstrate that Teva intentionally and knowingly sought to conceal its illegal conduct.

188. Teva concealed its efforts to induce private plan payors to pay for Copaxone by paying pharmacies to not collect cost-sharing obligations from private health plan members and by causing pharmacies to report the full, undiscounted drug price when submitting claims to PBMs and private health plans. The specialty pharmacies with which Teva conspired also falsely represented in their contracts with PBMs that they would collect participant cost-sharing payments as a condition for submitting pharmacy claims. Teva and the specialty pharmacies knew that health plans enforce participant cost-sharing obligations through agreements entered into between PBMs and their network pharmacies and engaged in an intentional scheme to defraud private health plans to interfere with and circumvent these cost controls.

189. Teva misrepresented why it introduced 40mg Copaxone and otherwise concealed its true motive of avoiding generic substitution. Teva represented that 40mg Copaxone was more convenient, but internal Teva discussions and documents indicate this was merely a "generic



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defense strategy" to "minimize[e] generic substitution," that Teva knew the change in dosage "does not represent a significant improvement in convenience," that there was "no supporting data for the selected dose or dosing regimen," that Teva's data "do not support going to higher doses," that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value," and that Teva was in search for a pretextual justification for changing dosages. Teva nonetheless engaged in an extensive outreach campaign, with the assistance of PBMs, to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone.

190. Teva concealed its efforts to conspire with PBMs to make Copaxone the exclusive or prioritized drug on formularies and to conspire with specialty pharmacies to have generic prescriptions filled with Copaxone.

191. Teva's fraudulent concealment prevented Plaintiffs and the Class from discovering this conduct. Plaintiffs remained unaware of it until the Government filed its complaint in August 2020 and the House of Representatives released its report in September 2020.

192. **Continuing Tort:** Defendants are estopped from relying on any statute of limitations defense because their illegal, deceptive, and fraudulent practices as alleged herein, which are continuing, have created continuing and repeated injuries to Plaintiffs and the Class.

## VI. CLASS ACTION ALLEGATIONS

### A. Class Definitions

193. Pursuant to provisions of the Federal Rules of Civil Procedure ("Rule") 23(a), (b)(2), and (b)(3), Plaintiffs bring this action on behalf of themselves and a proposed national class of other similarly situated entities (collectively, "the Nationwide Class"), defined as follows:

> **Nationwide Class:** All entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of prescription drugs prescribed to natural persons covered by such contract, policy, or plan ("plan members"), and who paid and/or provided reimbursement



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for some or all of the purchase price for Copaxone[28] prescribed to plan members at any time from 2006 until the effects of Defendants' unlawful conduct cease.

194. In addition to the Nationwide Class and pursuant to Rule 23(c)(5), Plaintiffs seek to represent the following Washington State Subclass as well as any subclasses or issue classes Plaintiffs may propose and/or the Court may designate at the time of class certification:

> **Washington Subclass**: All entities in Washington State that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of prescription drugs prescribed to natural persons covered by such contract, policy, or plan ("plan members"), and who paid and/or provided reimbursement for some or all of the purchase price for Copaxone prescribed to plan members at any time from 2006 until the effects of Defendants' unlawful conduct cease.

195. Excluded from the Class and Subclass are:

a. Defendants and their subsidiaries, and affiliates;

b. Federal and state governmental entities except for tribes, cities, towns, municipalities, counties, or other units of local government that have self-funded health plans that cover prescription drugs; and

c. Fully insured health plans (i.e., plans that purchased insurance from another entity that covered 100% of the plan's reimbursement obligations to its members).

196. Plaintiffs reserve the right to revise the definitions of the Class and Subclass based upon information learned through discovery.

**B. Requirements of Rule 23**

197. The Class consists of tens of thousands health plans, and other payors throughout the United States and is therefore so numerous and geographically dispersed that it would be impractical to join all Class Members before the Court.

198. There are numerous and substantial questions of law or fact common to all of the members of the Class and which predominate over any individual issues. Included within the common question of law or fact are:

[28] As used herein, "Copaxone" refers to both the 20mg/ml and 40mg/ml doses of Copaxone.



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a. Whether Defendants engaged in a course of conduct that improperly induced Plaintiffs and the Class to pay for Copaxone and improperly increased the amounts Plaintiffs and the Class paid for plan members' MS treatment;

b. Whether Defendants engaged in a pattern of deceptive, fraudulent and/or improper activity intended to defraud Plaintiffs and the Class;

c. Whether Defendants formed enterprise(s) for the purpose of effectuating their deceptive and fraudulent schemes;

d. Whether Defendants' enterprise(s) used the U.S. mail and interstate wire facilities to carry out their deceptive and fraudulent schemes;

e. Whether Defendants' enterprise(s) engaged in a pattern of racketeering;

f. Whether Defendants' deceptive and fraudulent schemes, in whole or in part, have substantially affected interstate and intrastate commerce;

g. Whether Defendants engaged in conduct that violated the federal racketeering laws as alleged herein;

h. With respect to the Washington Subclass, whether Defendants' conduct was unfair or deceptive, in violation of the Washington Consumer Protection Act;

i. Whether Plaintiffs and the other members of the Class were injured by Defendants' conduct and, if so, the appropriate class-wide measure of damages;

j. Whether Defendants were unjustly enriched; and

k. Whether Plaintiffs and the other members of the Classes are entitled to injunctive relief.

199. The claims of the Plaintiffs are typical of the claims of Class Members, in that they share the above-referenced facts and legal claims or questions with Class Members, there is a sufficient relationship between the damage to Plaintiffs and Defendants' conduct affecting Class Members, and Plaintiffs have no interests adverse to the interests of other Class Members.

200. Plaintiffs will fairly and adequately protect the interests of Class Members and have retained counsel experienced and competent in the prosecution of complex class actions including complex questions that arise in consumer protection litigation.



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201. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:

a. Absent certification of the Class, the Class Members will continue to suffer damage and Defendants' unlawful conduct will continue without remedy while Defendants profit from and enjoy their ill-gotten gains;

b. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendants committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;

c. When the liability of Defendants has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and

d. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiffs and members of the Class can seek redress for the harm caused to them by Defendants.

202. Because Plaintiffs seek relief for the entire Class, the prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Defendants.

203. Further, bringing individual claims would overburden the Courts and be an inefficient method of resolving the dispute, which is the center of this litigation. Adjudications with respect to individual members of the Class would, as a practical matter, be dispositive of the interest of other members of the Class who are not parties to the adjudication and may impair or impede their ability to protect their interests. As a consequence, class treatment is a superior method for adjudication of the issues in this case.



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## VII. CLAIMS

### FIRST COUNT — VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(c) (on behalf of Plaintiffs and the Class)

204. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

205. Plaintiffs bring this Count on behalf of themselves and the Class.

206. At all relevant times, the Defendants have been "persons" under 18 U.S.C.§ 1961(3).

207. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

208. For many years, the Defendants sought to increase sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Class to pay for Copaxone instead of alternative MS drugs. Finding it impossible to achieve their ambitious goals lawfully, however, the Defendants resorted to cheating through their fraudulent scheme and RICO conspiracy.

#### 1. The Copaxone Enterprise

209. The illegal scheme was developed and executed by Teva together with a number of other entities, including ACS, AssistRx, CDF, TAF, PBMs, and specialty pharmacies. These persons and entities, along with their corporate parents, siblings, subsidiaries, employees, and agents, as well as other entities and individuals, were employed by or associated with, and conducted or participated in the affairs of, one or several RICO enterprises (referred to collectively as the **"Copaxone Enterprise"**).

210. The identity of the specific PBMs and specialty pharmacies that participated in the Copaxone Enterprise are unknown because of Defendants' and their co-conspirators' acts to



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conceal their misconduct. The House Committee's report addresses Teva's collusion with PBMs and specialty pharmacies but did not disclose the identities of the specific entities involved and agreed to redact the names of such entities from documents excerpted in their public report.[29] As noted above, three PBMs—Express Scripts, CVS, and OptumRx—serve the overwhelming majority of the market and these three PBMs each have their own in-house specialty pharmacies. On information and belief, one or more of these three PBMs and one or more of their specialty pharmacies are the PBMs and specialty pharmacies involved in the Copaxone Enterprise.

211. The Copaxone Enterprise is as an association-in-fact enterprise, within the meaning of 18 § U.S.C. § 1961(4), whose activities have affected interstate commerce. It was an ongoing organization that functioned as a continuing unit from at least 2006 until the present. It was formed and utilized to effectuate a pattern of racketeering activity. Teva, ACS, AssistRx, CDF, TAF, the PBMs, the specialty pharmacies, and the other entities and individuals involved in the Copaxone Enterprise are each "persons" distinct from the Copaxone Enterprise.

212. The Copaxone Enterprise was formed and operated for the purpose of effectuating a fraudulent scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Class to pay for Copaxone at an inflated price instead of purchasing alternative MS drugs.

213. Each Defendant and co-conspirator knowingly participated in the Copaxone Enterprise and conducted the activities relevant to its respective role in the scheme.

214. Teva, in coordination with ACS and Assist Rx, illegally subsidized the copays of Medicare recipients and illegally sought to circumvent the prohibitions of the Anti-Kickback Statute and the False Claims Act by funneling money through CDF and TAF. Teva made contributions to the foundations in the specific amounts necessary to subsidize the co-pays for Copaxone patients and engaged in a variety of conduct in coordination with ACS, Assist Rx, CDF, and TAF to ensure that its "donations" would be used exclusively for Copaxone patients.

[29] *See* House Report at 38 n.137.



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ACS and AssistRx steered Copaxone patients to CDF and TAF and served as a conduit for information, providing Teva with information necessary to calculate the amounts of its donations and providing CDF and TAF with the batch files necessary to match the Teva dollars with Copaxone patients. CDF and TAF knowingly used Teva's donations to fund copay assistance for Copaxone rather than for other MS drugs and provided information to ACS and AssistRx to enable Teva to calculate the specific amount of its "donations."

215. Defendants knew the illegal subsidization of the cost-sharing payments of Medicare recipients would undermine the price-checking function of the cost-share obligations required under Medicare and would induce Medicare plans to pay for units of Copaxone despite the excessive and ever-increasing amounts Teva charged for the drug. Defendants further knew this scheme would allow Teva to inflate the single Copaxone list price for all payors, including private health plan payors.

216. Teva, in coordination with pharmacies and specialty pharmacies, defrauded private health plans by using copay coupons to inflate the price of Copaxone and to induce private health plan payors to spend excessive amounts on Copaxone. Teva coordinated with pharmacies and specialty pharmacies to have them accept coupon cards in lieu of cost-sharing payments from private health plan members on the condition that Teva would remit to the pharmacies and specialty pharmacies payment for the amount of the foregone cost-sharing payments. This scheme effectively provided the pharmacies and specialty pharmacies with a discount on the price of Copaxone. But the pharmacies and specialty pharmacies submitted false claims to PBMs and ultimately private health plans for the full, undiscounted price of Copaxone, causing private health plan payors to make payments based on the undiscounted price.

217. By deceptively relieving private health plan members of their obligations to pay cost-sharing payments for Copaxone, Teva and its co-conspirators knew they were undermining the price-checking function of cost-share obligations required by private health plans and were



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inducing private health plan payors to pay for units of Copaxone despite the excessive and ever-increasing amounts Teva charged for the drug.

218. Teva, in coordination with PBMs, defrauded private health plans by introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing plans to continue paying for high priced Copaxone instead of lower cost generic forms of glatiramer acetate. Teva enlisted PBMs to contact patients and physicians to encourage them to switch from 20mg Copaxone to 40mg Copaxone before generic versions of 20mg glatiramer acetate became available. Teva and its co-conspirators knew that if they converted private health plan members over to 40mg Copaxone before 20mg generics entered the market, pharmacists would not be allowed to fill Copaxone prescriptions with lower cost generics and thus private health plan payors would be forced to continue paying for Copaxone despite its high price.

219. Teva, in coordination with PBMs, specialty pharmacies, and prescribers, defrauded private health plans, and their members, to cause prescriptions to be filled with, and private plan payors to pay for, Copaxone instead of lower cost generics. Teva contracted with PBMs to make Copaxone the only version of glatiramer acetate that would be covered by health plans and paid them rebates and other fees as consideration. Teva further contracted with specialty pharmacies to have them fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs. Teva also conspired with physicians to have them write prescriptions with the notation "dispense as written," thereby undermining the ability of pharmacists to substitute lower cost generics when the more expensive Copaxone had been prescribed. Teva and its co-conspirators knew that this conduct would induce private health plan payors to pay for Copaxone instead of the alternative, lower cost generic forms of glatiramer acetate.

220. Teva asserted control over the Copaxone Enterprise by designing, organizing, and funding the above-described schemes.



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221. Within the Copaxone Enterprise, there are contractual relationships, financial ties, and continuing coordination activities between Teva and its co-conspirators. On information and belief, members of the Copaxone Enterprise have communicated repeatedly over several years to carry out their common purposes, and have entered into, monitored, and enforced contractual and/or agency arrangements regarding payment and the delivery of services.

222. Defendants knew that their scheme violated federal and state laws.

223. The Copaxone Enterprise engaged in and affected interstate commerce because, among other things, it marketed, sold, distributed, or provided Copaxone across state lines to thousands of individuals throughout the United States and induced thousands of private health plan payors throughout the United States to pay for Copaxone. The illegal conduct and wrongful practices carried out by members of the Copaxone Enterprise were effectuated by an array of employees, working across state boundaries, who necessarily relied upon frequent transfers of documents and information, products, and funds through the U.S. mail and interstate wire facilities.

**2. The Pattern of Racketeering**

224. To carry out the scheme to defraud, Teva and its co-conspirators knowingly participated, directly or indirectly, in the conduct of the affairs of the Copaxone Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and which employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

225. Teva's and its co-conspirators' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: Teva and its co-conspirators violated 18 U.S.C. § 1341 by engaging in an unlawful scheme to defraud involving false pretenses, misrepresentations, promises, and omissions. In furtherance of this scheme, the Defendants used the mail.

b. Wire Fraud: Teva and its co-conspirators violated 18 U.S.C. § 1343 by engaging in an unlawful scheme to defraud involving false pretenses, misrepresentations, promises,



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and omissions. In furtherance of this scheme, the Defendants used the interstate wires.

c. Violations of the Travel Act: Teva and its co-conspirators violated 18 U.S.C. § 1952(a) by traveling in interstate or foreign commerce, and by using the mail and other facilities in interstate or foreign commerce, with the intent to distribute the proceeds of an unlawful activity and to promote, manage, establish, carry on, or facilitate the promotion, management, establishment, or carrying on, of an unlawful activity. The illegal kickbacks Teva and its co-conspirators provided to Medicare recipients constituted "unlawful activity" within the meaning of 18 U.S.C. § 1952(b) because they amounted to bribery in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1).

**a. Defendants' Fraudulent Acts and Misrepresentations**

226. ***Medicare False Claims*:** Teva and its co-conspirators engaged in and orchestrated an elaborate scheme to defraud Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare.

227. Teva made sham "donations" to CDF and TAF that were ostensibly intended to benefit all MS patients for all MS drugs but were in fact narrowly targeted to subsidize cost-sharing obligations of Copaxone patients covered by Medicare plans, in violation of the Anti-Kickback Statute.

228. ACS, as the specialty pharmacy that filled the majority of Copaxone prescriptions, further submitted false claims records when it filled Copaxone prescriptions that it knew were induced by Teva's illegal kickbacks. The insurers who sponsor and contract with the government to provide Medicare plans enter into subcontracts with pharmacies who fill prescriptions for Medicare recipients. When a pharmacy dispenses a drug to a Medicare recipient, the pharmacy submits an electronic record of the claim, known as a Prescription Drug Event ("PDE"), to the Centers for Medicare & Medicaid Services ("CMS"). Pharmacies and other "downstream" or "related" entities that subcontract with Medicare plans are required to comply with the False Claims Act and Anti-Kickback Statute, and all other federal laws, regulations, and CMS instructions, 42 C.F.R. §§ 423.505(h)(1), (i). CMS regulations require that



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the pharmacies and other "downstream" entities that generate and submit PDEs must certify that the PDEs are true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the healthcare products or services reflected therein. *Id.* §§ 423.505 (i), (k). In conjunction with each Copaxone prescription it filled to a patient using copay assistance from CDF or TAF, ACS certified false claims and PDEs because it knew the claims were induced by illegal kickbacks. The government submitted representative samples of PDEs reflecting false claims for which Medicare provided reimbursement for the purchase of Copaxone by a Medicare recipient who used an illegal copay subsidy from Teva via CDF or TAF. A copy of the government's exhibit reflecting these representative claims is attached hereto as Exhibit 4.

229. ***Private Copay Coupons*:** Teva further conspired with pharmacies and specialty pharmacies to defraud private healthcare plans by using copay coupons to inflate the price of Copaxone and to induce health plans to spend excessive amounts on Copaxone, including by manipulating and interfering with the health plans' cost-sharing structures.

230. By accepting monies from Teva in the amount of copay coupons in lieu of charging participants for their cost-sharing obligations, the pharmacies and specialty pharmacies transmitted to the PBMs and ultimately to Plaintiffs and the Class false information about the total cost of Copaxone. For example, if a health plan requires participants to pay $100 out of the total cost of each prescription fill, in the case of a $500 drug, a health plan—via its PBM—will reimburse the pharmacy for the full cost less $100 (e.g., $400). If the drug manufacturer paid the $100 copayment on behalf of the participant (i.e., reduced the pharmacy's drug cost by $100), the actual cost charged by the pharmacy was only $400, not $500, meaning the plan should have paid only $300 ($400 less the $100 copay). By submitting a claim to the plan reflecting a total drug price of $500, the pharmacy transmitted false information to the PBMs and ultimately to the health plans, causing health plan payors to pay more for the drug than they would have had the pharmacy properly collected the participant's copayment. The same is true of a health plan that imposes percentage coinsurance. For example, if a health plan imposes a 20 percent coinsurance



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obligation, a health plan—via its PBM—will reimburse the pharmacy $400 for a $500 drug. If the drug manufacturer paid the $100 coinsurance obligation on behalf of the participant (i.e., reduced the pharmacy's drug cost by $100), the actual cost charged by the pharmacy was only $400, and the plan would have been responsible for paying only 80 percent of that amount (i.e., $320). By submitting a claim reflecting a total drug price of $500, the pharmacy transmitted false information to the PBMs and ultimately to the health plans, causing the health plan payors to pay more for the drug than they would have had the pharmacy properly collected the participant's copayment.

231. Because they effectively waived plan participants' obligations to pay their cost-sharing payments, the specialty pharmacies also falsely represented in their contracts with PBMs that they would collect participant cost-sharing payments as a condition for submitting pharmacy claims. Teva and the specialty pharmacies knew that health plans use cost-sharing obligations to control spending on expensive brand drugs and to keep a check on prescription drug prices. Teva and the specialty pharmacies further knew that health plans enforced these provisions through agreements entered into between PBMs and their network pharmacies. Teva and the specialty pharmacies engaged in an intentional scheme to defraud health plans to interfere with and circumvent these cost controls, causing health plan payors to pay undiscounted rates for subsidized drugs and to pay for more prescriptions of the subsidized drugs than they would have paid absent the Copaxone Enterprise's conduct related to private copay coupons.

232. ***Product Switch*:** Teva, in collusion with PBMs, further engaged in an intentional scheme to defraud health plans by introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws and thus inducing health plan payors to continue paying for high priced Copaxone instead of lower cost generic forms of glatiramer acetate. Teva misrepresented the reasons for the introduction of 40mg Copaxone and engaged in an extensive outreach campaign through its sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone. Although Teva represented that 40mg



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Copaxone was more convenient, internal Teva discussions and documents reflect that this was merely a "generic defense strategy" to "minimize[e] generic substitution," that Teva knew the change in dosage "does not represent a significant improvement in convenience," that there was "no supporting data for the selected dose or dosing regimen," that Teva's data "do not support going to higher doses," that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value," and that Teva was in search for a pretextual justification for changing dosages. Teva further entered into contracts with PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg alternatives hit the market.

233. ***Other***: Teva, in collusion with PBMs and specialty pharmacies, also engaged in a scheme to defraud patients and health plans to cause health plans to purchase unwanted doses of Copaxone instead of alternative generics.

234. Teva contracted with PBMs—and paid them rebates as consideration—to make Copaxone the only version of glatiramer acetate that would be covered by health plans.

235. Teva contracted with specialty pharmacies to fill generic glatiramer acetate prescriptions with Copaxone without patients' knowledge, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs. These pharmacies went so far as to place Copaxone within a plain box to obscure the fact that generic prescriptions were being filled with Copaxone.

236. Although lower-cost, generic glatiramer acetate is the same active ingredient used in Copaxone and may be substituted by pharmacists as "therapeutically equivalent" to Copaxone, Teva sent misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients



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that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month,[30] in contravention of the requirements of the participants' health plans.

**b. Defendants' Use of Mail and Wires**

237. Teva and its co-conspirators repeatedly used the mail and wires to effectuate their scheme. As set forth in more detail above in the factual allegations, examples of their use of the mail and wires include, but are not limited to:

a. Teva routinely communicated with ACS and AssistRx through the mail and/or wires to coordinate the timing and amounts of "donations" to CDF and TAF to fund copay assistance for Copaxone patients on Medicare plans;

b. Teva routinely transmitted sham "donations" to CDF and TAF using the mail and/or wires;

c. Teva, ACS, AssistRx, CDF, and TAF routinely exchanged information with each other using the mail and/or wires, including information reflecting the numbers of Copaxone patients awaiting copay assistance and the per-patient grant amounts;

d. ACS and AssistRx routinely used the mail and/or wires to transmit to CDF and TAF batch files reflecting the names of Copaxone patient awaiting copay assistance;

e. Teva routinely used the mail and/or wires to refer Copaxone patients to ACS and AssistRx and ACS and AssistRx subsequently used the mail and/or wires to refer Copaxone patients to CDF and TAF;

f. CDF and TAF routinely used the mail and/or wires to transmit copay assistance funds to Copaxone patients and/or to pharmacies on behalf of Copaxone patients;

g. ACS and other pharmacies that filled Copaxone prescriptions for Medicare recipients who used copay assistance from CDF and TAF routinely submitted false Copaxone claims to Medicare Plans using the mail and/or wires and submitted PDEs reflecting these false claims to CMS using the mail and/or wires;

[30] *See, e.g., Here with Proactive Prescription Tips,* Copaxone, https://www.copaxone.com/injection-assistance/copaxone-generic (last visited Mar. 28, 2021).



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h. Teva routinely used the mail and/or wires to communicate with participants of private health plans regarding copay "coupon" cards and to transmit such cards to these participants;

i. Teva routinely used the mail and/or wires to transmit funds to pharmacies and specialty pharmacies for the amount of copay "coupons" used by private health plan participants;

j. Pharmacies and specialty pharmacies routinely used the mail and/or wires to transmit claims information to PBMs (and ultimately health plans) that misrepresented the actual cost of Copaxone prescriptions for which the pharmacies and specialty pharmacies received payment from Teva in conjunction with the use of private copay coupons;

k. Teva used the mail and/or wires to pressure PBMs to make 40mg Copaxone available in health plan formularies;

l. Teva and the PBMs used the mail and/or wires to contact patients and physicians to encourage them to switch from 20mg Copaxone to 40mg Copaxone before generic versions of 20mg glatiramer acetate became available on the market;

m. Teva used the mail and/or wires to pressure PBMs to make Copaxone the preferred or only version of glatiramer acetate covered under health plan formularies;

n. Teva regularly transmitted rebates and other payments to PBMs through mail and/or wires as consideration for their agreements to convert patients to 40mg Copaxone and to make Copaxone the preferred or only version of glatiramer acetate covered under health plan formularies;

o. Teva used the mail and/or wires to pressure specialty pharmacies to fill generic glatiramer acetate prescriptions with Copaxone;

p. Teva communicated with doctors through mail and wires to persuade them to write prescriptions with the DAW notation;

q. Teva systematically sent emails and/or made phone calls to all Copaxone patients with DAW messaging; and

r. Teva electronically transmitted lists of Copaxone patients to health care professionals to allow them to "proactively" write DAW prescriptions.



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**c. Defendants' "Unlawful Activity" In Violation of the Travel Act**

238. The Anti-Kickback statute makes it a crime to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person … to purchase … any good, … or item for which payment may be made in whole or in part under a Federal health care program …." 42 U.S.C. § 1320a-7b(b)(2).

239. A drug manufacturer violates the Anti-Kickback statute if it subsidizes co-insurance and other cost-sharing obligations incurred by Medicare recipients.

240. Teva and its co-conspirators funneled over $300 million through CDF and TAF—non-profits that served as pass-through vehicles—so that Teva could subsidize the cost-sharing obligations of Medicare recipients. This financial assistance was made available to Medicare recipients if, and only if, such recipients purchased Copaxone; Teva and its co-conspirators went to great lengths to ensure that Teva's financial assistance was not made available for the purchase other MS drugs. In other words, Teva and its co-conspirators knowingly and willfully paid remuneration (including kickbacks and bribes) to Medicare recipients to induce them to purchase Copaxone for which payment was made by Medicare plans.

241. Teva knew its conduct constituted violations of the Anti-Kickback statute and knew that it could not use CDF and TAF as pass-through vehicles to circumvent the Anti-Kickback statue.

242. Because this conduct amounted to bribery in violation of the Anti-Kickback Statute, it constituted "bribery … in violation of the laws … of the United States" and thus was "unlawful activity" within the meaning of the Travel Act. 18 U.S.C. § 1952(b).

243. Teva and its co-conspirators further traveled in interstate or foreign commerce and/or used the mail and facilities in interstate or foreign commerce with the intent of distributing the proceeds of their unlawful activity, including using the proceeds to pay service fees to ACS and AssistRx. Moreover, as detailed above, Teva and its co-conspirators further



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traveled in interstate or foreign commerce and/or used the mail and facilities in interstate or foreign commerce with the intent of promoting, managing, establishing, carrying on, or facilitating the promotion, management, establishment, or carrying on, of their unlawful activity.

**3. Causation and Damages**

244. As a direct and proximate result of their fraudulent scheme and common course of conduct, Teva and its co-conspirators illegally extracted revenues of millions or billions of dollars from Plaintiffs and the Class. As explained in detail herein, their years-long misconduct violated RICO Section § 1962(c).

245. By reason of, and as a result of the conduct of Teva and its co-conspirators, and in particular, their pattern of racketeering activity, Plaintiffs and Class Members have been and continue to be injured in their business and/or property.

246. The effect of Defendants' and their co-conspirators' racketeering activity was to induce sales of Copaxone that otherwise would not have been made in the absence of their illegal conduct and to maintain or raise the price of Copaxone to a higher level than it would have commanded in the absence of the illegal conduct.

247. Plaintiffs and the Class suffered injuries when they paid for Copaxone prescriptions that otherwise would not have been made and/or paid higher prices than they would have paid but for the illegal conduct of Teva and its co-conspirators.

248. Teva's and its co-conspirators' violations of 18 U.S.C. § 1962(c) have directly and proximately caused injuries and damages to Plaintiffs and the Class.

249. By virtue of these violations of 18 U.S.C. § 1962(c), Teva and its co-conspirators are jointly and severally liable to Plaintiffs and the Class for three times actual damages, plus costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c). Plaintiffs are further entitled to seek injunctive and other appropriate equitable relief.



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**SECOND COUNT — CONSPIRACY TO VIOLATE THE RICO ACT, 18 U.S.C. § 1962(d)**
**(on behalf of Plaintiffs and the Class)**

250. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

251. Section 1962(d) provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

252. Defendants and their co-conspirators violated 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Copaxone Enterprise through a pattern of racketeering activity.

253. Teva and its co-conspirators engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, as alleged *supra* ¶¶ 223-242.

254. Defendants and their co-conspirators have sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail fraud in violation of 18 U.S.C. § 1341;

b. Multiple instances of wire fraud in violation of 18 U.S.C. § 1343; and

c. Multiple violations of the Travel Act, 18 U.S.C. § 1952(a).

255. The purpose and effect of the conspiracy was to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Class to pay for Copaxone at an inflated price instead of purchasing alternative MS drugs. This further allowed Teva and its co-conspirators to create profits that could be shared among the conspirators.

256. The nature of the conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of the conspiracy to violate 18 U.S.C. § 1962(c), but also that they were aware that their ongoing



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fraudulent, manipulative, and coercive acts have been and are part of an overall pattern of racketeering activity.

257. As a direct and proximate result of Teva's and its co-conspirators' overt acts and predicate acts in furtherance of their conspiracy to violate 18 U.S.C. § 1962(c), Plaintiffs and the Class have been injured in its business and property as set forth more fully above.

258. Plaintiffs and the Class suffered injuries when they paid for Copaxone prescriptions that otherwise would not have been made and/or paid higher prices than that would have but for the illegal, conspiratorial conduct of Teva and its co-conspirators.

259. By virtue of these violations of 18 U.S.C. § 1962(d), Teva and its co-conspirators are jointly and severally liable to Plaintiffs and the Class for three times actual damages, plus costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c). Plaintiffs are further entitled to seek injunctive and other appropriate equitable relief.

**THIRD COUNT — VIOLATIONS OF THE WASHINGTON CONSUMER PROTECTION ACT**
**(on behalf of Plaintiffs and the Washington Subclass)**

260. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

261. Plaintiffs bring this action on behalf of themselves and the Members of the Washington Subclass.

262. Defendants, Plaintiff, and the Members of the Washington Subclass are "persons" within the meaning of Wash. Rev. Code § 19.86.010(1).

263. Defendants are engaged in "trade" or "commerce" within the meaning of Wash. Rev. Code § 19.86.010(2).

264. The Washington Consumer Protection Act ("Washington CPA") makes unlawful "unfair or deceptive acts or practices in the conduct of any trade or commerce." Wash. Rev. Code § 19.86.020.



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265. Defendants engaged in unfair and deceptive acts and practices in violation of the Washington CPA in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for alternative MS drugs.

266. As set forth in more detail above in the factual allegations, examples Defendants' unfair and deceptive acts and practices include but are not limited to:

a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

c. Using copay coupons to undermine the price-checking function of cost-share obligations imposed by private health plans, thus manipulating the purchasing decisions of private health plan members and inducing private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for alternative MS drugs;

d. Causing pharmacies and specialty pharmacies to transmit false information about the cost of Copaxone to PBMs and private health plans, including by obscuring the discount the pharmacies received from Teva, thus inducing private health plan payors to make payments based on the undiscounted price of Copaxone;

e. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower cost generic forms of glatiramer acetate;

f. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

g. Concealing that the product switch was part of a "generic defense strategy" to "minimize[e] generic substitution," that Teva knew the change in dosage



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"does not represent a significant improvement in convenience," that there was "no supporting data for the selected dose or dosing regimen," that Teva's data "do not support going to higher doses," that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value," and that Teva was in search for a pretextual justification for changing dosages;

h. Contracting with PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg alternatives hit the market;

i. Contracting with PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the formularies that determine which drugs will be covered by private health plans, thus manipulating the choices available to patients and doctors and inducing private health plan payors to pay excessive amounts for Copaxone instead of paying for alternative MS drugs;

j. Contracting with specialty pharmacies and, on information and belief, providing specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

k. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

l. Concealing from the public Teva's unfair and deceptive practices which lead to and permitted its Copaxone price increases and its inducement of payments from private health plan payors;

m. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and ACS, AssistRx, TAF, CDF, PBMs, specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

n. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.



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267. Defendants owed and continue to owe Plaintiffs and the Washington Subclass a duty to refrain from the above-described unfair and deceptive practices and to disclose the true nature of the pricing of Copaxone.

268. Defendants knew or should have known that their conduct was in violation of the Washington CPA.

269. Defendants intentionally and/or knowingly omitted and/or misrepresented material facts regarding Copaxone, their efforts to increase sales and inflate the price of Copaxone, and their efforts to manipulate the prescribing and purchasing decisions of doctors and patients, all with the intent to mislead Plaintiffs and the Subclass and to induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for alternative MS drugs. Despite knowing the true nature of their practices for years, Defendants continued to engage in unfair and deceptive practices in violation of the Washington CPA.

270. Defendants' unfair and deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for alternative MS drugs.

271. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Defendants' material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other unfair and deceptive practices by Defendants proximately caused Plaintiff and the Subclass to pay for Copaxone instead of alternative MS drugs and to overpay for Copaxone.

272. Plaintiffs and the Subclass suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Defendants' unfair and deceptive practices and



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omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for alternative MS treatments. Defendants' violations also present a continuing risk to Plaintiffs and other private health plan payors in Washington, who provide health coverage for thousands of Washingtonians afflicted by MS. Defendants' violations further present a continuing risk to the general public, who in many cases are unable to afford or gain access to affordable treatment for MS. As such, Defendants' unlawful acts and practices complained of herein affect the public interest.

273. Pursuant to Wash. Rev. Code § 19.86.090, Plaintiff and the Subclass seek an order enjoining Defendants' unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Washington CPA. Because Defendants' actions were willful and knowing, Plaintiffs' damages should be trebled. *Id.*

**FOURTH COUNT — UNJUST ENRICHMENT**
**(on behalf of Plaintiffs and the Class)**

274. Plaintiffs repeat and re-allege every allegation above as if set forth herein in full.

275. Plaintiffs bring this claim on behalf of themselves and the Class under the common law of all U.S. states and territories.

276. By reason of their conduct, Defendants caused damages to Plaintiffs and to Members of the Class.

277. By purchasing the Copaxone at an inflated price, which Teva forced them to do, Plaintiffs and the Class Members conferred a benefit on Teva in the form of the inflated and unconscionable prices they paid for Copaxone.

278. Teva appreciated the benefit because, had consumers not purchased Copaxone, Teva would have no sales and derive no benefit from sales of Copaxone.



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279. Teva was directly involved in setting the price, making material misstatements, and directing the sale and distribution of Copaxone nationwide in the United States.

280. Defendants' acceptance and retention of the benefit is inequitable and unjust because the benefit was obtained by Teva's price gouging, unconscionable sales, and unlawful acts, as set forth above.

281. Equity cannot in good conscience permit Teva to be economically enriched for its unjust actions at Plaintiffs' and Class Members' expense and in violation of state law, and therefore restitution or disgorgement or both of such economic enrichment is required.

## VIII. PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully request the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3) and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Class;

B. Require Teva to pay for sending notice to the certified Class;

C. Appoint Plaintiffs as Class Representatives and Plaintiffs' counsel as Class Counsel;

D. Issue an injunction to enjoin Teva from engaging in the deceptive, unfair, unconscionable, and unlawful business practices alleged in this Complaint;

E. Award further injunctive relief, as the Court deems appropriate;

F. Award compensatory damages to Plaintiffs and the proposed Class in an amount to be established at trial, or, alternatively, require Defendant to disgorge or pay restitution in an amount to be determined at trial;

G. Award treble damages as permitted by law;

H. Award pre- and post-judgment interest;

I. Award punitive damages based on Teva's reprehensible and deliberate conduct;

J. Award reasonable attorneys' fees and costs; and,

K. Award all such other and further relief as may be just and proper.



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## IX. DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims so triable.

DATED this 8th day of April, 2021.

KELLER ROHRBACK L.L.P.

By *s/ Lynn Lincoln Sarko*
By *s/ Gretchen Freeman Cappio*
By *s/ Matthew M. Gerend*
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